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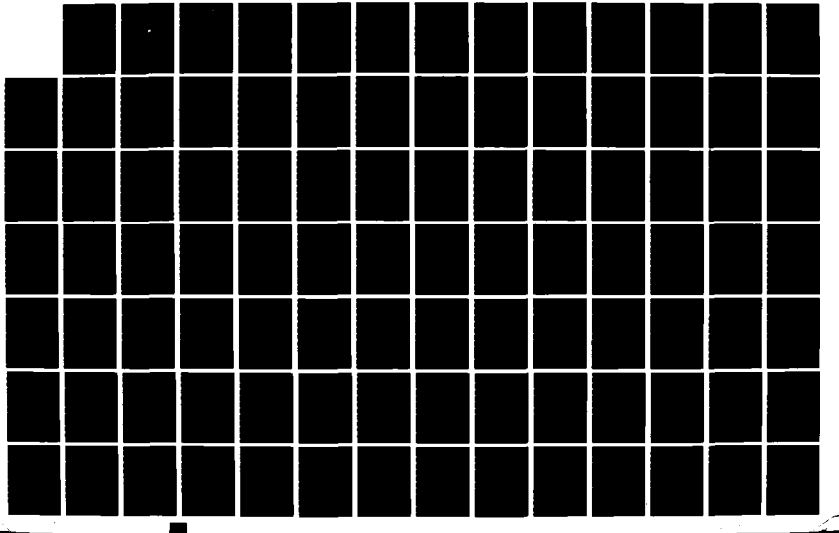

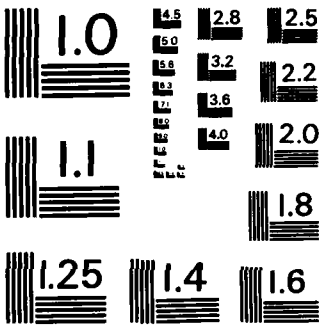

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NAVAL POSTGRADUATE SCHOOL
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THESIS

QUALITY ASSURANCE/RISK MANAGEMENT
IN THE NAVAL MEDICAL COMMAND

by

William Emory Wallace

and

James Louis Dillard

September 1985

Thesis Advisor: David Richard Whipple, Jr.

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Quality Assurance/Risk Management in the Naval Medical Command

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requirements for the degree of

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ABSTRACT

The purpose of this thesis is to assess the Navy Medical Command Quality Assurance/Risk Management Program. As part of this analysis the authors have conducted an extensive literature review of quality assurance publications. An in-depth analysis of the Navy Medical Command quality assurance instruction is provided. The Joint Commission on Accreditation of Hospitals quality assurance publications were compared with the Naval Medical Command Quality Assurance instruction. The authors noted deficiencies in the Navy Medical Command instruction with respect to meeting Joint Commission on Accreditation of Hospitals quality assurance program accreditation standards. Additionally, suggestions have been included to improve the overall effectiveness of the Naval Medical Command quality assurance instruction. A set of "key variables" were developed as a means for assessing the adequacy of an existing Navy military treatment facility quality assurance program.

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I. INTRODUCTION

The phrase "quality of care" is vague and has acquired various emotional overlays. This is to be expected since, quality is related to the complexities of medical care, and, in the final analysis, absolute standards can be defined only in relation to levels of individual and community health attainment. These standards are arbitrary and measure relative quality of care through comparison with actual achievement. Some people use the words "quality of care" interchangeably with the quality of life. Notions of liberty and happiness as well as health are connoted by the single phrase. Others assume that almost any measurement in the health field which shows improvement implies that quality of care has improved.

There are four major influences on health: (a) the medical care system, (b) genetics, (c) the environment, and (d) patient behavior. We will be concerned only with measures of those components of health that can be altered by the medical care process and are considered indicators of quality of care. Quality of life and quality of care are therefore not considered synonymous. [Ref. 1]

Quality assurance programs in the Navy are designed to evaluate patient care and to identify and correct deficiencies found in the patient care process. Included in the scope of

quality assurance is risk management. Risk management is an integrated program designed to: (1) recognize the causes of iatrogenic injury and (2) manage the events subsequent to the occurrence of an iatrogenic injury.

Key to an understanding of risk management are the concepts of iatrogenic injury and potentially compensable events. Iatrogenic injury generally refers to an abnormal state or condition produced by the physician or the health care institution in a patient by inadvertent or erroneous treatment. Iatrogenic injuries may be divided further into categories of those which are unavoidable and those which are avoidable. Avoidable iatrogenic injuries are recognized in QA/RM programs as being potentially compensable events (PCE'S). [Ref. 2]

Recent articles, news broadcasts and Congressional hearings have focused on assertions of inadequate quality of care provided in the military health care system. Although "quality" is difficult to define, one indicator of the quality of care is the incidence of malpractice suits resulting in settlements or judgments against the defendant. The Navy Judge Advocate General LEGAL ADVISOR'S HANDBOOK FOR MEDICAL RISK MANAGEMENT states that as of 1982 there had been an average of approximately 750 medical malpractice claims a year filed against the military health care system. This publication further states that in the past few years, the settlement of such claims administratively has approached $20 million a year. Claims that were not settled at the

claims stage, but were referred to the Justice Department for litigation were also expensive.

In 1979, the Justice Department paid out approximately $7 million for claims involving the military health care system. In 1980, there were 79 litigated malpractice judgments against the government regarding care provided by practitioners in military treatment facilities (MTFs) which resulted in $10.5 million paid to plaintiffs. In 1981, this number rose to 123 litigated judgments costing a total of $15 million. These figures do not include the extensive resource costs (i.e., medical, administrative and legal) involved in adjudicating a claim. These resource costs are substantial and can add $50 million to the cost of adjudicating claims. Thus, malpractice claims against the military are costing the government a total of $75 million per year with increases expected in 1982. [Ref. 3]

The statistics cited above were obtained from legal documentation covering a period ending in 1982. Subsequent events have indicated that problems within the Navy health care system have not only continued, but have increased in severity as well. Navy physicians were responsible for 84% of liability claims paid by the Navy in 1983. [Ref. 4] No facility is exempt from quality control problems and prestige is no harbinger of quality. A recent national network television broadcast documented the removal of the Chief of Cardiology at the National Naval Medical Center in

Bethesda, Md. for failure to adhere to accepted Navy quality assurance standards. [Ref. 5]

The Secretary of Defense, in a 26 January 1983 letter to the Assistant Secretary of Defense for Review and Oversight, expressed concern that a problem might exist in the health care quality assurance program, especially in the area of credentialed health care provider performance reviews. The DOD Inspector General (DODIG) office was tasked on 1 February 1983, to conduct a DOD-wide survey of the quality of health care at Medical Treatment Facilities (MTFs). [Ref. 6]

The DOD audit was conducted from May 1983 to September 1983 at the headquarters of the medical departments and at six military hospitals (two in each Service). The objectives of the DODIG audit were to evaluate administrative and personnel staffing procedures and records used by the military hospitals for granting privileges to health care providers, for controlling emergency room functions, and for supervising physician assistants. DODIG also evaluated procedures used by recruiting in the Services to screen and accept health care providers. The DODIG audit revealed problems with procedures for granting medical privileges to health care providers, lack of treatment protocols/inadequate procedural documentation in emergency rooms, and inconsistent procedures for supervising and evaluating performance of physicians assistants.

At a joint meeting held in March 1983, DODIG, Air Force, and Army audit representatives identified twenty-two areas of medical concern. In a 1 June 1983 Memorandum for the Auditor General, the Secretary of the Navy authorized the Naval Audit Service to participate in a survey for the purpose of defining the potential scope and objectives of an audit of military health care within the Navy. As a result of these recent Navy health care quality control failures, the cost of malpractice has become of significant concern to senior officials within the Department of the Navy (DON). The Under Secretary of the Navy approved the audit scope, objectives and site selection on 30 August 1983.

The overall audit objectives of the Naval Audit Service were to assess the adequacy of policies, programs, and the management controls over quality assurance and incident reporting concerning health care providers at six Navy hospitals. [Ref. 7] As a result of this audit, several deficiencies were discovered with regard to MTF credentialing, boards and committees/quality assurance programs, incident reporting/ risk management, inpatient medical records, emergency medical services, and utilization review.

The authors have conducted an extensive analysis of the Navy Medical Command's Quality Assurance/Risk Management program. During the course of this analysis the authors compared the Navy's Quality Assurance program to quality assurance standards provided by the Joint Commission for Accreditation

of Hospitals (JCAH), the primary hospital accreditation organization in the United States. As such, JCAH has established quality assurance program standards which all U.S. hospitals, both military and civilian, strive to meet, and moreover, must meet in order to obtain accreditation by the JCAH.

In the comparative analysis chapter of the thesis, the authors examined various components of the Navy Quality Assurance/Risk Management Program in an attempt to determine if discrepancies exist. The methodology of this analysis involved comparing specific components of the current Navy Quality Assurance Instruction (NAVMEDCOMINST 6320.7) with the corresponding components found in pertinent JCAH publications. The authors have provided recommendations for improvement in the quality assurance/risk management program. These recommendations for improvement were based upon both discrepancies noted during the comparative analysis and additional deficiencies perceived by the authors.

During the second phase of our analysis, the authors reviewed several recent malpractice suits against the Navy Medical Command. The authors used information provided by the medical malpractice litigation review, and visits to NAVMEDCOM, two GEONAVMEDCOMS, and a major naval treatment facility, to develop a set of "key variables" for use as a management control tool. The authors intend these "key variables" as a tool to enable a manager or auditor to assess the performance of an existing quality assurance program.

The final chapter of the thesis contains concluding recommendations to assist NAVMEDCOM in achieving its stated goal of providing the best quality of patient care within the resources available.

II. MEDICAL QUALITY ASSURANCE/RISK MANAGEMENT LITERATURE REVIEW

A. METHODOLOGY OF LITERATURE REVIEW

An extensive literature review was conducted using JCAH, American College of Hospital Administrators (ACHA) and the American Hospital Association (AHA) as authoritative sources of medical quality assurance/risk management information.

The structure of the information provided by the civilian sources was not always found to be categorically identical with the structure of the Navy instruction. This presented problems with regard to a direct topical comparison of the Navy's quality assurance program with those recommended by the civilian organization.

The civilian organizations typically disclaimed any responsibility resulting from direct implementation of their recommendations during establishment of medical quality assurance programs. However, they did provide useful examples for establishing such programs. These examples have been utilized extensively by facilities which have successfully passed JCAH accreditation surveys. JCAH is the primary accrediting agency in both military and civilian health care systems. We chose to use both their quality assurance accreditation standards and quality assurance program examples in our analysis of the effectiveness of the Navy's quality assurance program.

B. OVERVIEW OF JCAH QUALITY ASSURANCE PUBLICATIONS

Publications of the JCAH are designed for health care professionals who seek and maintain voluntary accreditation in general acute care hospitals; psychiatric or mental health, long term care, and ambulatory health care facilities; and hospice service programs. In addition to standards for each of these areas of health care, JCAH publishes related documents that assist facilities in assessing their practices and procedures in preparation for an accreditation survey. JCAH also publishes educational program reference/resource materials which address such areas as quality assurance and safety. [Ref. 8]

Within this purview of JCAH information exist several quality assurance publications which were utilized during the preparation of this thesis. A brief description of the information provided in each of these JCAH quality assurance publications is discussed below.

1. JCAH QA Guide--A Resource for Hospital Quality Assurance

The QA Guide, published in January, 1981, was designed to help hospitals meet the intent of the quality assurance standard and to develop and implement comprehensive, problem-focused approaches to quality assurance that have a positive impact on the quality of patient care and clinical performance. The QA Guide addresses the importance of organizing a flexible quality assurance program that meets the unique needs of a hospital.

The JCAH quality assurance standard for hospitals is designed to help health care professionals develop a more sophisticated, comprehensive approach to quality assurance activities. The standard, which became effective for accreditation decision purposes on January 1, 1981:

(1) emphasizes the value of a coordinated, hospital-wide quality assurance program;

(2) allows greater flexibility in approaches to problem identification, assessment, and resolution;

(3) emphasizes the importance of focusing quality assurance activity on problems whose resolution will have a significant impact on patient care and outcomes;

(4) encourages the use of multiple data sources to identify problems; and

(5) discourages the use of quality assurance studies only for the purpose of documenting high quality care.

The QA GUIDE is designed to help hospitals meet the intent of the quality assurance standard and to develop and implement comprehensive, problem-focused approaches to quality assurance that have a positive impact on the quality of patient care and clinical performance. [Ref. 9] The first five chapters of the QA Guide are designed to assist a hospital staff assess its current activities, and to organize an effective, comprehensive quality assurance program. The QA GUIDE provides guidance for hospital staffs in the following areas:

(1) setting goals and objectives for quality assurance;

(2) assessing current quality assurance activities;

(3) analyzing assessment results;

(4) using assessment results as a basis for organizing the hospital-wide quality assurance program;

(5) developing a quality assurance plan; and

(6) implementing the quality assurance program.

Chapters 6 through 10 of the QA GUIDE discuss a problem-focused approach to quality assurance and provide assistance for:

(1) using multiple data sources for problem identification;

(2) determining priorities for problem assessment and resolution;

(3) selecting and implementing appropriate assessment methods;

(4) establishing clinically valid criteria; and

(5) selecting appropriate sample sizes. [Ref. 10]

Chapter 11 discusses annual reevaluation of the program and suggests questions that might be useful in assessing the results of a hospital's quality assurance program.

Additionally, the QA GUIDE discusses the necessity for a problem-focused approach to the quality assurance activity. The interpretation of the quality assurance standard states that

> to obtain maximal benefit, any approach to quality assurance must focus or the resolution of known or suspected problems (that impact directly or indirectly on patients) or, when indicated, on areas with potential for substantial improvements in patient care.

A quality assurance program that results in problem resolution depends on explicit, knowledgeable use of a logical approach to problem solving. The following five basic components of

quality assurance activity constitute a logical approach to problem solving:

(1) identify problems;

(2) determine priorities for problem assessment and problem resolution;

(3) establish clinically valid criteria and select appropriate assessment methods;

(4) establish problem causes most amenable to correction, and plan and implement corrective actions; and

(5) evaluate and monitor problem resolution.

Any quality assurance activity, whether simple or complex, should be based on the problem-solving logic delineated above. However, these five components are not steps that must be rigidly followed to meet accreditation requirements or rules that outline the "right" or the "only" approach to quality assurance, nor do these components imply that new forms for quality assurance activities are in the offing. The five components of quality assurance activity are a set of guidelines for quality assessment that are based on logical principles of evaluation and that are most likely implicit (i.e., not written) in many quality assurance activities already. However, the components should become an explicit part of the hospital's quality assurance activities because, when clearly spelled out and acknowledged, they can be used to evaluate whether the program is planned and implemented effectively. Flexibility in the depth and speed of application of the components is both appropriate and acceptable; that is, although the components should be

considered in problem solving, it is not necessary to isolate and apply each component in a strict methodological sense.

A comprehensive problem-focused approach to quality assurance will only be successful if identified problems are resolved and if resolution of problems is sustained. The impact of the program on patient care and clinical performance should be assessed, and the effectiveness of the overall program should be evaluated on a regular basis. [Ref. 11]

2. JCAH Back to Basics--An Introduction to Principles of Quality Assurance

The Back to Basics manual was introduced in 1982 by JCAH in order to clarify quality assurance requirements. It attempted to alter the then prevalent concept that "quality assurance is just another way of performing medical audits." After completion of an extensive literature review on medical quality assurance materials, it is the authors' opinion that BACK TO BASICS is the most complete and comprehensive publication available for use as a resource in establishment and maintenance of a quality assurance program.

Long before the Quality Assurance Standard was approved in 1979, JCAH standards required the implementation of various quality assessment mechanisms by the medical staff, nursing and clinical ancillary services. As early as 1953, medical staffs were required to review the quality of medical care including surgical cases, the quality of the medical record, and to delineate clinical privileges for each staff member. With the advent of the Medicare legislation in 1965, standards

for utilization review, standards for surveillance of infections and pharmacy and therapeutic practices were added. In 1970, a major rewrite of JCAH standards was completed that explicitly required the medical staff to perform medical care evaluation, to review the use of blood, appropriateness of surgery and to perform a pharmacy and therapeutics function which included examination of drug use. In 1975, numerical requirements for the conduct of patient care evaluation ("audits") were introduced. In 1976, standards for infection control and antibiotic usage review appeared as well as explicit language requiring the review of care by clinical ancillary services.

Yet despite the evolution of these multiple quality related standards, greater emphasis in JCAH's survey process, in education programs and publications was given to medical audit requirements which presented a prescriptive methodology for reviewing care. This emphasis and the adoption of medical audit requirements by the Professional Standards Review Organization (PSRO) program elevated audit as the quality assurance mechanism.

By 1978, it became apparent that medical audit activities did not improve patient care to the extent anticipated. Furthermore, survey data indicated that other quality related activities of the medical staff and support services were performed perfunctorily, in isolation, or not at all. JCAH recognized that a purposeful integration of these

activities as well as a mechanism to oversee their effective conduct was necessary.

JCAH eliminated audit requirements in 1979 and introduced a new quality assurance standard which was much less prescriptive than the audit requirements. More importantly this standard was designed to stimulate the creation of a hospital-wide quality assurance program involving the ongoing, systematic monitoring of care, identification of problems in quality, and resolution of these problems. The quality assurance standard is unique in that it molds pre-existing standards that focus on the review of specific aspects of care with new requirements to coordinate various quality assurance activities into an organized program focused on identifying and resolving problems in patient care or clinical performance. With the addition of this new standard, JCAH has the following quality assurance requirements:

GENERAL PROVISIONS

(1) The governing body is responsible for the quality of care in the hospital.

(2) The governing body delegates responsibility to the professional and administrative staff for establishing a hospital-wide quality assurance program and assuring its effectiveness.

(3) This program is guided by a written plan which describes the objectives, structures, and operation of the quality assurance program.

(4) The scope of the quality assurance program covers all areas of direct patient care.

(5) Clinically valid criteria are used in the evaluation of patient care.

(6) To avoid duplication of effort and assure adequate attention to problems which affect more than one

area of the hospital, mechanisms are in place to assure appropriate communication across departments and services and adequate follow through on identified problems.

(7) The QA program observes the effectiveness of individual quality review mechanisms.

(8) The structure and effectiveness of the program are evaluated and adjusted at least annually. [Ref. 12]

BACK TO BASICS also addresses specific review requirements for JCAH accreditation of a quality assurance program. This JCAH publication outlines the following quality review activities which should be part of a hospital's quality assurance program:

(1) Review of Credentials and Granting of Privileges. The medical staff periodically must review the credentials and recommend the granting of privileges for each medical staff member. This should involve an evaluation of the current competence of each practitioner and recommendations as to which procedures he can perform in the hospital.

(2) The medical staff must establish continuous monitors of relevant aspects of their practice including:

(a) Ongoing Antibiotic Review--to examine the appropriateness of the prophylactic and therapeutic use of antibiotics;

(b) Monthly Surgical Case Review--to examine the appropriateness of surgical procedures and discrepant cases;

(c) Quarterly Medical Record Review--to examine the timely completion, clinical pertinence and adequacy of content of the medical record;

(d) Quarterly Pharmacy and Therapeutics Review--to review and maintain drug formularies, review drug utilization, investigate drug reactions, and establish policies and procedures for the distribution and handling of drugs;

(e) Quarterly Blood Utilization Review--to examine the appropriateness of the use of blood and blood products and transfusion reactions;

(f) Monthly Review of Care by Medical Staff Departments--to review the care and treatment of patients including such areas as morbidity, mortality, infections and other treatment complications, and unusual or interesting cases;

(g) Enforcement of the Rules and Regulations of the Medical Staff--to assure that medical staff members are abiding by the policies of its own organization.

(3) Hospital-Wide Functions of:

(a) Infection Control--to identify and evaluate nosocomial infections and establish and monitor aseptic and sanitation practices;

(b) Utilization Review--to examine the appropriateness of admission, length of stay and identify any utilization-related problems in diagnoses, procedures, or practitioners;

(c) Preventive Maintenance--to assure the safety and reliable performance of all equipment relating directly or indirectly to patient care.

(4) Review and evaluation of the quality and appropriateness of nursing care;

(5) Review and evaluation of the quality and appropriateness of patient care rendered by the following clinical support services:

(a) Anesthesia Services, Dietetic Services, Emergency Services, Home Care Services, Hospital-Sponsored Ambulatory Care Services, Nuclear Medicine Services, Nursing Services, Pathology and Medical Laboratory Services, Radiology Services, Rehabilitation Services, Respiratory Care, Social Work Services and Special Care Units. [Ref. 13]

The aforementioned review requirements are considered essential components of a sound quality assurance program, and as such, represent the minimum requirements for development of a treatment facility's quality assurance program.

BACK TO BASICS states that the QA standard was not introduced to add some new quality assurance activity to the

existing cadre of quality protective functions mentioned above, but rather to encourage an organized approach, e.g., program, to review care throughout the hospital and medical staff and to provide an oversight mechanism to assure that individual functions are conducted rigorously and effectively. Three key features are critical to the success of a hospital-wide quality assurance program:

(1) COMPREHENSIVENESS. All departments, services, committees, functions, and providers involved in the provision of care to patients participate in quality assurance activities.

(2) INTEGRATION OR COORDINATION OF QUALITY ASSURANCE ACTIVITIES. Relevant information generated from QA activities is shared with appropriate hospital and medical staff, departments, committees and administration so that action can be taken at the right level to solve identified problems.

(3) A PROBLEM-FOCUSED APPROACH. In the conduct of individual QA activities, approaches that identify, examine, and resolve problems are used. Four fundamental components characterize this process:

    (a) Examination of key indicators or aspects of quality care;

    (b) Verification or assessment of suspected problems or concerns in care delivery to determine their cause, how pervasive they are and which departments are involved;

    (c) Implementation of corrective action;

    (d) Monitoring or follow up to determine the effectiveness of actions taken. [Ref. 14]

While the authors recognize that the problem-focused approach described immediately above is not directly identical to the problem-focused approach mentioned in the JCAH QA GUIDE, we feel the differences exist in semantics, not substance. The

(10) To continually monitor the impact and efficacy of

BACK TO BASICS text was a JCAH response to survey data which indicated that little improvement in the quality or effectiveness of individual hospitals occurred as a result of the introduction of a QA standard in 1979. Other sources have noted similar findings. As a result of these findings, JCAH introduced BACK TO BASICS as a non-prescriptive, yet more definitive set of guidelines for the establishment of a medical quality assurance program.

3. JCAH Ambulatory Health Care Standards Manual (AHC/85)

JCAH recognizes the importance of maintaining standards that reflect current practice and the dynamic nature of health care today. Maintaining such standards is particularly important for the ambulatory health care field, which is expanding and diversifying in an attempt to meet the growing need for a variety of health care services in the United States. The standards contained in the Ambulatory Health Care Standards Manual are applicable to a wide range of ambulatory health care organizations, including community health centers, group practices, health maintenance organizations, urgent care centers, ambulatory surgery centers, college or university health services, uniformed services clinics, and emergency centers. Most standards are stated in broad, general terms so that ambulatory health care organizations can meet them by using methods most suitable to their particular circumstances. When methods of complying with a standard are limited, the standard is stated in more specific terms.

Whether a standard is general or specific, however, the determination of compliance depends on evidence of substantial fulfillment of the purpose and intent of the standard. The degree and number of variations, as well as the importance of a particular deficiency in a specific organization, are considered in making the overall accreditation decision. The existence of the following four elements are of primary importance in the decision-making process:

(1) Health services that demonstrate a high quality of care;

(2) A quality assurance program that systematically monitors and evaluates the quality and appropriateness of patient care;

(3) A diagnostic summary in each patient's medical record; and

(4) Legible entries in each patient's medical record.

Although these standards are the most important in terms of the granting of accreditation, all the standards are considered in reaching a final decision; that is, compliance with these four elements alone does not necessarily result in a decision of accreditation.

All the standards contained in the AMBULATORY HEALTH CARE STANDARDS MANUAL are presented in an outline format that helps organize and clarify the content of the standards. Each of the 15 chapters begins with a statement of a standard and, under that statement, specific required characteristics against which an ambulatory health care organization's fulfillment of the standard will be measured.

In addition to providing the standards and required characteristics to be used during a JCAH accreditation survey, the AMBULATORY HEALTH CARE STANDARDS MANUAL is designed for use as a self-assessment tool. An organization can easily assess its level of fulfillment of each standard or required characteristic by using a rating system provided in the manual. [Ref. 15]

C. OVERVIEW OF NAVAL MEDICAL COMMAND INSTRUCTION 6320.7, GUIDE FOR QUALITY ASSURANCE (NAVMEDCOMINST 6320.7, 6 SEPT 1984)

For comparative purposes, the following explanation provides an analogy between the structural hierarchy of a civilian hospital and that of the Naval Medical Command. The Commander, Naval Medical Command, Washington, D.C. is the President of the Board of Trustees (governing body) with the commanders of geographic naval medical commands, and commanding officers of medical treatment facilities and dental treatment facilities (DTF's) as regional and local representatives, respectively. Commanding officers assume the added responsibility of chief executive officer (CEO) at those MTF's participating in JCAH accreditation programs. [Ref. 16]

The following overview of the GUIDE FOR QUALITY ASSURANCE is somewhat detailed, as the authors shall continuously refer to this section in the comparative analysis section of our thesis. It is felt the reader should have a comprehensive understanding of the GUIDE FOR QUALITY ASSURANCE prior to proceeding with the comparative analysis section.

The stated purpose of the GUIDE FOR QUALITY ASSURANCE is to promulgate requirements for establishing comprehensive, commandwide, quality assurance programs in all naval hospitals, medical clinics, and dental clinics.

The GUIDE FOR QUALITY ASSURANCE implies biphasic action: (1) to evaluate the degree of excellence of the results of delivered care; and (2) to make improvements so that care in the future will result in a higher degree of quality. Quality assurance activities reflect what patients and providers expect of each other. In past years, various means of reviewing and evaluating patient care have been introduced by the Joint Commission of Accreditation of Hospitals (JCAH) including the Performance Evaluation Procedure (PEP) for auditing and improving patient care. The PEP audits failed to coordinate quality related activities, and the potential for these audits to display improvement in patient care became lost in a paper shuffle exercise. In 1979, the JCAH Board of Commissioners approved the JCAH ACCREDITATION MANUAL FOR HOSPITALS, which eliminated the ineffectual numerical requirements for PEP audits, and imposed the requirement for hospitals to coordinate quality assurance activities and to use an ongoing monitoring system to review and evaluate the quality and appropriateness of care. This approach is effective in identifying important patient realted problems and is applicable in every health care delivery situation. Many of the principles, standards, and organizational requirements of the JCAH ACCREDITATION MANUAL FOR HOSPITALS and JCAH AMBULATORY

HEALTH CARE STANDARDS MANUAL have been adopted and are contained in QUIDE FOR QUALITY ASSURANCE as required elements for QA programs of naval hospitals, medical clinics, and dental clinics. [Ref. 17]

The QUALITY ASSURANCE GUIDE states that Commanding Officers of naval hospitals, medical clinics, and dental clinics shall establish a quality assurance program in accordance with the QUALITY ASSURANCE GUIDE. They shall be responsible for the leadership, motivation, and education of the staff on the subject of quality and for the organizatoin, implementation and ongoing monitoring of the quality assurance program. All patient care services of the command shall participate in the review and evaluation of the quality and appropriateness of clinical care and services rendered. Requirements of the QA program are that each command shall:

(1) Establish budget funding for staff QA education and library reference materials.

(2) Assign qualified personnel to manage QA program.

(3) Establish the following required committees for naval hospitals:

    (a) Quality assurance committee.

    (b) Executive committee of the medical staff.

    (c) Infection control committee.

    (d) Safety committee.

    (e) Special care units committee.

    (f) Ambulatory health care committee (multidisciplinary).

(4) Write a QA plan that realistically describes the command-wide QA program.

(5) Establish individualized QA plans for each clinical and ancillary department to ensure that quality assurance monitoring is being performed by staff responsible for care and that QA problems are being solved at the lowest level.

(6) Establish screening mechanisms throughout the system for detecting important patient related problems.

(7) Establish a facility-wide incident reporting system and submit semiannual summary reports of analyzed findings during reporting periods to commanders of geographic naval medical commands on 15 January and 15 July with Plan of Action and Milestones (POA&M) for corrective actions of noted potential problems, downward trends, etc.

(8) Conduct patient satisfaction surveys and submit semiannual summary reports of analyzed findings to commanders of geographic naval medical commands on 15 March and 15 September.

(9) Develop communication systems for facility-wide sharing and documentation of QA information.

(10) Evaluate the quality assurance program at least annually.

Commanders of geographic naval medical commands shall assume intermediate QA program management responsibilities, establish monitoring mechanisms, and review and evaluate periodic reports submitted by subordinate commands. On-site QA assistance visits shall be conducted to determine compliance with this instruction, appraise the level of readiness for a Joint Commission accreditation survey, and gather firsthand information to prepare factual reports for higher authorities. They shall:

(1) Schedule semiannual onsite visits to each subordinate command.

(2) Submit to Commander, Naval Medical Command (MEDCOM-35) an annual regional QA assessment report (NAVMED 6010/20) with POA&M for correcting discrepancies. [Ref. 18]

The GUIDE FOR QUALITY ASSURANCE is prepared for use by all naval medical and dental treatment facilities (M/DTF'S) in developing a facility-wide quality assurance program that establishes an ongoing system for the review and evaluation of the quality and appropriateness of medical care rendered to beneficiaries. The mission of each naval M/DTF is to ensure that its patients receive the best possible health care its resources can provide. This can be confirmed only if the quality of care rendered is measured against or compared with preestablished, optimal, achievable standards of care that are measurable and adaptable for use in all naval M/DTF's. For these reasons, the Naval Medical Command has incorporated many of the compliance requirements of the Joint Commission for Accreditation of Hospitals standards in the formulation of policies, and the development of measuring tools for the ongoing monitoring and evaluation of the quality of patient care rendered by naval health care providers.

The underlying success of a quality assurance program is dependent upon the type and level of staff involvement. The greater the level of support from top management and key decision makers, the more direct and effective will be staff participation in QA activities. The motto for a successful QA program is: "Quality Assurance is Everybody's Business'"

The QUALITY ASSURANCE GUIDE consists of six sections, with specific sets of requirements for hospitals, medical clinics, and dental clinics. The intent is to require the level of the complexity of the QA program to be directly proportional to the complexity of the care provided. While sections of the QUALITY ASSURANCE GUIDE refer to hospitals, those same sections contain many concepts that are applicable to free-standing medical and dental clinics. [Ref. 19]

1. Section A--Principles and Methods for Establishing a Quality Assurance Program

a. Chapter 1. Overview of Compliance Requirements of Quality Assurance Standards for Naval/Dental Treatment Facilities

The first chapter contains general guidelines for the establishment of a quality assurance program, and specifically addresses the following key issues:

(1) The Commanding Officer is responsible for establishing, maintaining, and supporting, through the organization's administration and professional staff, an ongoing quality assurance program.

(2) The QA plan providing for the comprehensiveness and integration of the overall quality assurance program and for the delegation of responsibility for the various activities that contribute to quality assurance must be defined in writing.

(3) A committee, group, or individual must be responsible for administering or coordinating the quality assurance program.

(4) Quality assurance activities conducted throughout the organization must be integrated and coordinated to the maximum extent possible (this coordination should avoid duplication of effort).

(5) The quality assurance program must focus on the identification and resolution of suspected problems that have a direct and indirect impact on patient care.

(6) The quality assurance program must be flexible to permit innovations and variations in the assessment approaches.

(7) Clinically valid written criteria are to be used in the assessment of problems.

(8) When problems are identified, appropriate action must be taken to eliminate or reduce them.

(9) Mechanisms are to be established that will facilitate the ongoing reporting of the results of quality assurance activities to responsible staff members via chain of command.

(10) The quality assurance program must be reappraised at least annually through a designated mechanism. [Ref. 20]

b. Chapter 2. Organizational Guidelines for QA Program Planning

Chapter 2 of Section A provides guidelines for initating organizational changes that will display evidence of top management's direct involvement and total staff commitment in the establishment of an effective QA program. Although this section is written specifically for naval hospitals, the concepts are generally applicable to naval medical clinics and naval dental clinics as well.

c. Chapter 3. The Written QA Plan

Chapter 3 of Section A contains the requirement that each facility write a QA plan that describes the design and systems of its QA program, and clearly explains the organizational structure and the interrelationships of everyday quality assurance activities. This chapter is applicable to hospitals, medical clinics, and dental clinics.

Careful planning is the cornerstone of a good program. For best results, the written QA plan should be

tailored to the type, size, and organizational structure of the facility, and to the scope of the services provided. A good QA plan will answer the following questions:

(1) What are we going to do?

(2) How are we going to do it?

(3) Who is going to do it?

The written QA Plan should contain definitions and descriptions of at least the following issues. Goals and objectives of a QA program that are:

(1) Realistic and measurable.

(2) Related to all areas of practice.

(3) Related to the command's mission statement.

It should also contain mechanisms for assuring the comprehensiveness (scope) of the overall QA program. The emphasis of the QA program should be on clinical care areas and monitors. These mechanisms should include the following:

(1) Medical staff monitors.

(2) Support services review and evaluation of the quality and appropriateness of care.

(3) Review of credentials and granting of privileges.

(4) Monthly department meetings, and meeting of the staff as a whole for non-departmentalized medical staff.

(5) Facility-wide functions, including infection control, safety, utilization review, risk management, and preventive maintenance. [Ref. 21]

Also mentioned are mechanisms for assuring authority, accountability, and responsibility of the medical

staff and other professionals. Chapter 3 states that the plan should include:

(1) A statement that the commanding officer bears ultimate responsibility for the quality of care within the institution, and has final authority and responsibility of the assurance of a flexible, comprehensive, and integrated QA program.

(2) Delegation of responsibility and accountability for command wide QA program and its component parts.

(3) Delineation of responsibility for assuring that individual quality assurance activities are performed at specified intervals, e.g., a monthly review of patient care by clinical departments and the annual evaluation of the written QA plan. [Ref. 22]

Additionally, Chapter 3 states that mechanisms should be in place to assure integration for horizontal and vertical communication, reporting of quality assurance concerns, and documentation of the effectiveness of the overall program.

d. Chapter 4. Management of Command-Wide QA Program

Chapter 4 of Section A establishes specific qualifications, functions, responsibilities and accountability requirements of the key staff members who have been delegated authority by the commanding officer to establish and manage the command-wide QA program. As a minimum, the following key position assignments must be filled:

(1) Executive Officer. Shall be appointed as overall manager of the command QA program, chairman of the QA committee functions, and immediate supervisor of the QA coordinator and physician advisor/head for the purposes of overseeing the requirements outlined in this directive.

(2) Quality Assurance Coordinator. Must be a full-time position for all hospitals. Can be part-time for branch hospitals, large medical clinics, and dental clinics.

(3) Physician QA Advisor. Advisor position is a collateral assignment. Can be a full-time position. Should attend JCAH Medical Staff Issues workshop. Responsible for monitoring medical staff QA activities.

(4) Executive Committee of the Medical Staff. This is a high level decision-making body delegated the responsibility for coordinating and monitoring all of the medical staff quality assurance activities. The committee should be accountable to the commanding officer for the overall quality and efficiency of patient care in the facility.

(5) Quality Assurance Committee. To be established on the premises that: (1) QA problems will be solved at the lowest level by those responsible for the care provided and (2) the command-wide QA committee is to be a top management decision-making body for high level multidisciplinary problems and for monitoring the effectiveness of the overall QA Program. Membership of the QA committee should include at least the following individuals.

Executive Officer. (Chairman)
Directorate of Administration
Directorate for Nursing Service
Directorate for Medical Service
Directorate for Surgical Service
Directorate for Ancillary Services
Physicain QA Advisor
QA Coordinator
JAG Officer--special advisor (attends as required)
Others--selected attendees (relevant to problems)
[Ref. 23]

Since the quality assurance committee is accountable to the commanding officer, the QUALITY ASSURANCE GUIDE states that it should have authority to perform the following:

(1) Investigate problems and direct responsible parties to implement action.

(2) Use delegated authority indirecting medical or clinical staff and committees to complete investigations at specified times.

(3) Report to commanding officer, responsible parties that have not implemented recommended actions.

(4) Request monthly update reports on QA resolutions of problems from department heads, QA Coordinator, medical staff and others as needed.

(5) Initiate a quality assurance review investigation of any service or department base on concerns reflected by legal office or litigation claims, discrediting statements by news media, clustering of incident reports or patient complaints, Navy Inspector General, Medical recommendations, Navy audit recommendations, JCAH survey recommendations, etc. [Ref. 24]

As a set of general recommendations, the QUALITY ASSURANCE GUIDE provides the following operating guidelines for the QA Committee:

(1) To coordinate existing QA functions and departments within a hospital-wide QA program.

(2) To establish hospital wide information collection and feedback mechanisms.

(3) To establish formal methods for evaluating compliance with policies and procedures, standards of care, operational systems, implicit and explicit criteria, and committee responsibilities.

(4) To encourage communication among all departments, services, and recognition of that participation.

(5) To ensure participation from all departments, services, and disciplines and recognition of that participation.

(6) To work closely with unit QA coordinators and establish an effective link between the QA department and all departments, units, and disciplines.

(7) To track identified problems through patient care evaluation studies and utilization review studies, departmental review and evaluation records, problem-oriented committee minutes and reports, professional and patient education activities, and risk management and internal auditing activities.

(8) To change and improve behavior and clinical performance and practice patterns.

(9) To disseminate appropriate information on results of QA activities to staff and to higher authority as required or requested.

(10) To continually monitor the impact and efficacy of the program, and to conduct an annual reassessment of the overall improvement in patient care. [Ref. 25]

e. Chapter 5. Systems Approach to QA Problem Solving

Chapter 5 of Section A provides the methodology to implement the required comprehensive ongoing system approach in assessing quality assurance activities that have a positive impact on the quality of patient care and clinical performance.

The QUALITY ASSURANCE GUIDE states the following basic components of quality assurance which constitute a logical approach are to be used:

(1) Identify problems.

(2) Determine priorities for problem assessment and problem resolution.

(3) Establish clinically valid criteria and select appropriate assessment methods.

(4) Establish problem causes most amenable to correction and plan and implement corrective actions.

(5) Evaluate and monitor problem resolutions. [Ref. 26]

The QUALITY ASSURANCE GUIDE defines a problem as a deviation from an expected occurrence that cannot be justified as appropriate under the circumstances. Problems selected as the focus of quality assurance activities should have the characteristics of being resolvable and of having positive impact on patient care and outcomes. [Ref. 27]

The QUALITY ASSURANCE GUIDE describes components of the ongoing problem detection system as follows:

(1) Problem Identification.

(a) Use of Multiple Data Sources.

[1] Internal.
[2] External.

(b) Interpreation of Data Sources.

(2) Setting Priorities.

(a) Considerations that Affect Priority Setting.

[1] Impact of the problem on patient care.
[2] Number of patients affected.
[3] Duration of a problem.
[4] Number of services/departments involved.
[5] Relationship of problems.
[6] Impact of problems on Navy mission readiness.

(b) Mechanisms for Setting Priorities.

[1] Determined by organizational structure of QA program.
[2] Mechanisms used to determine how and who will set priorities should be simple.
[3] Priority setting can be accomplished by two approaches; formal or informal process.

(3) Problem Assessment.

(a) Methods for Problem Assessment.

[1] Document-Based Review.
[2] Observation Studies.
[3] Interviews and Surveys.
[4] Combination of Above Methods.

(b) Factors Influencing Selection of Assessment Methods.

[1] Number of Issues Involved.
[2] Number of Disciplines Involved.
[3] Type of Problem.
[4] Probable Extent of the Problem.
[5] Availability, Accessibility, and Quality of the Data.

(c) Selecting an Appropriate Sample for Study.

[1] Census.
[2] Sampling Technique.
[3] Particular Clinical Problem to be Examined.

(d) Statistical Concerns for Use of Sampling Techniques.

(4) Use of Clinically Valid Criteria.

(5) Use of Generic Screening Criteria.

(6) Determining Cause of Problems and Corrective Actions.

(7) Evaluating and Monitoring Problem Resolution. [Ref. 28]

f. Chapter 6. Recording and Reporting QA Information

Chapter 6 of Section A promulgates the requirement that information generated by problem focused QA activities shall be adequately recorded and shared with appropriate staff members, departments, committees, and administration for the complete integration/coordination of the QA program--for closing the information flow loop.

The QUALITY ASSURANCE GUIDE recommends adopting a three level communications plan for establishing QA Documentation and Information Management system for a QA Program. Because of the overwhelming information generated by QA programs, the objectives of a three level plan are to:

(1) Develop standardized methods for documenting and tracking QA activities.

(2) Develop ongoing approaches to motivate staff to identify and report problems that have critical impact on the quality of patient care or staff performances.

(3) Prevent problems from being lost or forgotten. [Ref. 29]

Level One of the communications plan consists of conducting periodic meetings of all participants in the QA program and reporting upon the review and evaluation of the quality and appropriateness of care at specified intervals. A local standardized format is to be developed for minutes of all QA meetings.

Level Two of the communications plan includes responsibilities of the QA Coordinator and Physician Advisor to utilize mechanisms for ensuring the integration and coordination of the overall QA program and to prevent duplication of effort.

Level Three describes the flow of information and recommended actions reaching the commanding officer via the executive officer, executive committee of the medical staff, QA committee, and the QA coordinator. [Ref. 30]

Additionally, this section addresses the requirement for confidentiality of all copies of minutes, reports, worksheets, and other data within the QA program. Two aspects of confidentiality are important. The first is preventing unnecessary or unauthorized disclosure to individuals or agencies outside the hospital. The second is preventing unauthorized, inadvertent, or unnecessary disclosure to individuals within the hospital. Policies describing procedures for maintenance and release of data, and other QA related information are described in this section of the QUALITY ASSURANCE GUIDE.

2. Section B--Medical Staff QA Functions and Activities

Section B of the QUALITY ASSURANCE GUIDE contains twelve chapters which serve to promulgate guidelines that describe medical staff required participation and responsibilities for QA monitoring activities.

a. Chapter 1. Introduction

Chapter one of Section B states that since the medical staff is an essential force for maintaining quality assurance, without the physician's committed participation and support there can be no quality assurance program. Lacking such support, the QA program will result in a meaningless exercise of paper shuffling.

The objectives of Section B are to:

(1) To create a better understanding of quality assurance by the medical staff.

(2) To emphasize that external accrediting agents are not trying to tell them how to practice medicine.

(3) To provide the medical staff with the tools to perform its quality assurance.

(4) To convince members of the medical staff they must accept their rightful leadership position for planning and implementing systems for ongoing evaluations for the improvement of patient care throughout the facility.

The QUALITY ASSURANCE GUIDE states that there must be an organized medical staff that has the overall responsibility for the quality of all medical care provided to patients, as well as for accounting to the commanding officer. Moreover, there must be periodic indepth reappraisal of each medical staff member to assure that each member is qualified for membership and strives to maintain an optimal level of professional performance. The medical staff must provide mechanisms for the regular review, evaluation, and monitoring of medical staff practice and functions.

Because the overall responsibility for the quality of medical practice rests with the medical staff, the individual staff member must be held accountable for the quality and appropriateness of care rendered to their patients. The medical staff must perform specific quality assurance functions in monitoring this practice; such as monthly clinical meetings, antibiotic usage review, blood utilization review, and pharmacy and therapeutics review. [Ref. 31]

b. Chapter 2. Principles, Policies, Organization

Chapter two of Section B contains information regarding the principles, policies and organization for medical staff involvement in the QA program. This chapter formalizes the requirement for attendance at quality assurance education programs to ensure that the medical staff possesses a working knowledge of the principles and processes for conducting QA activities and to introduce them to QA literature and reference materials. Chapter two also states that the command-wide QA coordinator is to be recognized by the medical staff as a resource person for guidance, and furthermore, that there should be acceptance and compliance with his or her directions and suggestions.

This chapter also addresses the fact that the medical staff of any medical treatment facility must have principles and policies by which to function. The QUALITY ASSURANCE GUIDE recognizes the medical staff bylaws, rules, and regulations as being the mutually agreed upon principles

and policies by which each member of the medical staff understands his or her rights and responsibilities. The QUALITY ASSURANCE GUIDE states that they [sic] are applicable to naval hospitals because of JCAH accreditation requirements, however, bylaws, rules and regulations should never be written solely to satisfy JCAH requirements. The medical staff bylaws should serve as the medical staff's quality assurance plan and fully describe the components of the medical staff's QA program and systems approach. Therefore, the medical staff bylaws constitute a working document of principles, policies, and procedures that are designed and developed to meet the specific requirements at an individual hospital and its medical staff. [Ref. 32]

The medical staff organization will have great bearing on how the medical staff will perform quality assurance activities. The decision to departmentalize (i.e., establish separate clinical departments of general surgery, orthopedics, urology, etc.) should be based on the following factors:

(1) The size of the facility.

(2) The number of clinical specialties and subspecialties within the facility.

(3) The multiple members of the medical staff practicing in the same specialty area.

If the medical staff is departmentalized, the head of each department is responsible for:

(1) Accountability to the directorate for all professional and administrative activities within the department.

(2) Surveillance of the professional performances of practitioners exercising privileges within the department.

(3) Implementation and maintenance of effective peer review and quality assurance activities within the department and in cooperation with, or in relation to others as appropriate.

(4) Conducting monthly clinical departmental meetings that assure a systematic review and evaluation of the quality and appropriateness of care rendered within the department is carried out with the use of screening mechanisms.

(5) Maintaining meeting records that include resultant recommendations, conclusions, and actions instituted. [Ref. 33]

c. Chapter 3. Establishment of Executive Committee of the Medical STaff in Hospitals

Chapter three of Section B states that there must be an executive committee of the medical staff to act for the medical staff and serve as a liaison between the medical staff and the hospital administration. The instruction requires that membership should be representative of the entire medical staff. The committee is required to meet at least monthly.

The function of the executive committee of the medical staff is to provide an oversight function as well as taking final action on certain recommendations. The committee holds overall responsibility for coordinating all medical staff quality assurance activities, for monitoring the peer review process, and for evaluating individual performances of the medical staff members. Specific activities, functions, and responsibilities relevant to quality assurance include:

(1) Fulfilling the medical staff's accountability to the commanding officer for the quality of the overall medical care rendered to the patients.

(2) Ongoing measuring and monitoring of medical staff performance and the delivery of patient care by reviewing recommendations and reports submitted by persons responsible for:

(a) Clinical department meetings
(b) Mortality and morbidity conferences
(c) Surgical case review
(d) Blood utilization review
(e) Credentials review and privileges delineation
(f) Medical staff bylaws revision
(g) Pharmacy and therapeutics function
(h) Infection control committee
(i) Safety committee
(j) Medical record review
(k) Utilization review
(l) Special care review
(m) Library and medical education committee
(n) Antibiotic usage review
(o) Reviews of support services under the direction of physicians
(p) Evaluation of care in emergency services and ambulatory care service
(q) Inspector General, Naval Medical Command inspection report
(r) Evaluation of JCAH accreditation status of the facility

(3) Analyzing and summarizing the above reports for problem identification.

(4) Initiating and pursuing corrective actions when appropriate in accordance with medical staff bylaws and approval of the commanding officer.

(5) Acting on the credentials committee recommendations relating to staff appointments, clinical privileges, etc.

(6) Ensuring that screening mechanisms have been developed that will produce valid peer review results.

(7) Ensuring that all physician directed clinical and support services have an organized QA plan and mechanisms developed for self-assessment and internal reviews and evaluations of the quality and appropriateness of care.

(8) Ensuring that medical staff related problems are solved at the lowest level and tasking persons responsible to solve them.

(9) Implementing the approved policies of the medical staff.

(10) Establishing open lines of communication with the entire medical staff for the sharing of QA information.

(11) Ensuring physician and dentist participation in the command-wide QA program. The function of the executive committee of the medical staff should be to motivate praticipation by:

(a) Providing medico-legal reasons for the importance of medical staff participation and demonstrating how quality assurance has a direct link to risk management issues.

(b) Providing data that clearly states the problems [Ref. 34]

The QUALITY ASSURANCE GUIDE requires that the minutes for the exeuctive committee of the medical staff be complete and that written records be maintained on file. The instruction further states that only multidiscipline and administrative problems be forwarded to the command QA committee for discussion and resolution.

d. Chapter 4. Overview of Medical Staff Activities

The fourth chapter states that as part of the hospital's quality assurance program, the medical staff must strive to assure the provision of high quality patient care through the use of mechanisms designed to monitor and evaluate the quality and appropriateness of patient care provided. Additionally, it states that opportunities to improve patient care are to be addressed.

The medical staff is to provide effective, measurable mechanisms to monitor and evaluate the quality and appropriateness of all aspects of patient care, and the clinical performance of all individuals with delineated

clinical privileges. The instruction states that important problems in patient care are to be identified and resolved.

The medical staff must establish a coordinated system for implementing and monitoring all requisite QA activities, and each function should not exist in isolation from the other. Opportunities to improve care are to be addressed and accomplished through the following functions:

(1) Clinical Meetings
(2) Surgical Case Review
(3) Pharmacy and Therapeutics
(4) Medical Records Review
(5) Blood Utilization Review
(6) Antibiotic Usage Review
(7) Infection Control Committee
(8) Multidisciplinary Hospital Safety Committee
(9) Disaster Planning
(10) Anesthesia
(11) Emergency Services
(12) Hospital-Sponsored Ambulatory Care
(13) Nuclear Medicine
(14) Pathology and Medical Laboratory
(15) Radiology
(16) Rehabilitation
(17) Respiratory Care
(18) Special Care [Ref. 35]

Furthermore, each clinical service must assume responsibility for carrying out its QA function. The instruction requires that a person be assigned to organize, coordinate, and monitor the departmental QA program. Since many of these functions are dependent upon the size of the facility, the organizational structure may vary. However, there must be documented evidence that each function is being performed in compliance with accreditation requirements.

e. Chapter 5. Monthly Clinical Service or Department Meetings

Chapter five of Section B discusses the contents of and requirements for medical staff monthly clinical service or department meetings. The instruction states that the head of each department shall insure a regular review and evaluation of the quality and appropriateness of patient care rendered within the department, and that these are conducted through designated mechanisms and as a planned and systematic process.

The QUALITY ASSURANCE GUIDE requires monthly departmental meetings of major clinical services (or monthly medical staff meetings for nondepartmentalized medical staffs) to review and evaluate the care and treatment rendered to the patient population. Furthermore, the instruction requires that a record be maintained that includes resultant recommendations, conclusions, and actions instituted as a result of the review and evaluation. It is required that there be continuous monitoring with enforcement of those elements of patient care in noncompliance with the medical staff or clinical department or service rules and regulations.

Chapter five lists the rationale for QA program requirements for the medical staff as follows:

(1) Assures that objective peer assessment of patient care and clinical performance is carried out in a timely manner.

(2) Provides a system for maximal medical staff participation in these peer assessment activities.

(3) Demonstrates the medical staff accountability to the commanding officer for the quality of patient care rendered.

(4) Demonstrates medical staff assuming responsibility for peer review and QA monitoring function.

(5) Provides a problem focused review of important clinical issues or problems that impact on patient care and clinical performances. [Ref. 36]

The agenda for monthly clinical service or department meetings should include a discussion of at least the following:

(1) Mortality and morbidity review

(2) Case reviews

(3) Results of use of criteria (Occurrence or Generic Screening)

(4) Statistical data

(5) Reported information from other QA activities

(6) Available resources

(7) Monthly reports

In summary, the head of the department is responsible for assuring the implementation of a planned and systematic process for monitoring and evaluating the quality and appropriateness of the care and treatment of patients served by the department and the clinical performance of all individuals with clinical privileges in that department.

f. Chapter 6. Pharmacy and Therapeutic Review

Chapter six of Section B describes the medical staff Pharmacy and Therapeutics Review function. It states that this function is the responsibility of the medical staff

and shall be carried out in cooperation with the pharmacy department or service. The nursing department or service and administrative services are also required to participate. The review function must meet at least quarterly. Other QA requirements of the Pharmacy and Therapeutics function include:

(1) The development and surveillance of policies and procedures that relate to the selection of drugs, the intra-hospital distribution of drugs, and the safe administration of drugs.

(2) Monitoring and maintaining a current formulary.

(3) Drug utilization review within the facility.

(4) Review of adverse drug reactions.

(5) Review of protocols concerned with the use of investigational or experimental drugs.

(6) Maintaining written reports or minutes that reflect the results of all reviews and evaluations performed and actions taken. [Ref. 37]

Pharmacy department responsibilities include identifying study topics, developing and submitting criteria for the study, and participating in both committee review of the study results and formulating recommended corrective actions. Additionally, they participate in the design and implementation of a QA unit program that insures optimal drug utilization throughout the facility.

g. Chapter 7. Blood Utilization Review

Chapter seven of Section B describes the medical staff QA program requirements for Blood Utilization Review. The intent of the requirement is to establish whether or not a patient needed blood in some form, and if blood was required,

did the patient receive the proper form, and to use clinically valid criteria to assess whether or not the transfusions were justified.

The instruction requires that the medical staff report blood usage review at least quarterly, and such shall include the following:

(1) The monitoring and evaluation of the appropriateness of all transfusions, including the use of whole blood and blood products.

(2) The monitoring and evaluation of all confirmed transfusion reactions.

(3) The development or approval of policies and procedures relating to the distribution, handling, use, and administration of blood and blood components.

(4) The review of the adequacy of transfusion services to meet the needs of patients.

(5) The review of ordering practices for blood and blood products.

In addition, the instruction requires that screening mechanisms be used to identify problems in blood usage for more intensive evaluation. Clinically valid criteria are to be used in the screening process and for more intensive evaluation of any known or suspected problems in blood usage. Written reports of conclusions, recommendations, actions taken, and the results of actions taken are required to be maintained and recorded. [Ref. 38]

The QUALITY ASSURANCE GUIDE recommends the use of a committee in order to perform a blood utilization peer review process. Suggested membership should consist of no

more than eight members and should be multidisciplinary in nature. The primary objectives of this blood utilization peer review are:

(1) To assess the quality of care rendered to patients receiving transfusions.

(2) To develop a profile of blood usage.

(3) To monitor the use of component therapy.

(4) To provide a mechanism with which to determine the direction of staff education programs on blood utilization. [Ref. 39]

h. Chapter 8. Surgical Case Review

Chapter eight of Section B describes the medical staff QA requirements for surgical case review. The rationale for conducting an effective surgical case review is based upon these factors:

(1) Provides a method for reviewing essentially all surgical procedures with a minimum of medical staff effort.

(2) Ensures the appropriate utilization of surgical services.

(3) Determines whether complications that occurred could have been prevented.

(4) Confirms the medical necessity of surgical procedures performed.

(5) Uncovers patterns of practice which may need further study, e.g., unusual or repeated complications, or patients returning to surgery during the same hospital stay.

(6) Identifies problems relating to the appropriateness of clinical privileges.

The QUALITY ASSURANCE GUIDE requires that surgical case review be performed monthly by those departments or

services performing surgical procedures, or by a medical staff committee, to help assure that surgery performed in the hospital is justified and of high quality.

Surgical case review is conducted for each case, whether or not a tissue or specimen was removed. However, when surgical case review consistently supports the justification and appropriateness of individual surgical procedures or the surgical procedures performed by individual practitioners, the review of an adequate sample of cases is acceptable.

The instruction requires that all cases in which a major discrepancy exists between preoperative and postoperative (including pathologic) diagnoses be evaluated. Additional screening mechanisms based on predetermined criteria developed should identify types of cases that may be automatically excluded from the review process and, to identify other cases that require more intensive evaluation. [Ref. 40]

The QUALITY ASSURANCE GUIDE includes a plan of action for surgical case review which requires:

(1) Development of mechanisms and systems that indicate:

    (a) A requirement for a monthly evaluation of all surgical cases, whether or not a specimen is removed.

    (b) The medical staff, or committee of a surgical department have established clinically valid screening criteria for use in the review.

    (c) The system meets the problem focused peer review requirements.

    (d) Ambulatory surgical procedures, with or without specimens, performed both on the body externally and in association with endoscopy, with or

without local anesthesia, are included in the surgical case review function. The review will cover procedures performed by any credentialed practitioner.

(2) Write policy regarding specimens excluded from having to be sent to pathology.

(3) Gather no-specimen cases base line statistical data.

(4) Write clinically valid criteria for determining the medical necessity for no-specimen procedures.

(5) Determine the type of no-specimen cases that shall always need to be evaluated.

(6) Write criteria for specimen producing procedures.

(7) Complete the listing of surgical problems that are to be included in the surgical review.

(8) Develop agenda for surgical case review meeting.

(9) Maintain documented minutes of the surgical case review meeting.

(10) Conduct follow-up actions as required. [Ref. 41]

i. Chapter 9. Medical Record Review

Chapter nine of Section B sets forth the requirement that the quality of medical records shall be reviewed at least monthly for clinical pertinence and timely completion. Medical record review provides a systematic mechanism for evaluating and monitoring each medical staff member's practice. In addition, this review provides a systematic mechanism for conducting medical staff peer review based upon the supposition that:

(1) Excellent medical records are documents by which the performance of health care is measured.

(2) A complete medical record documents evidence of the course of the patient's illness and treatment as as well as justified diagnoses, treatment, and outcome. [Ref. 42]

Additionally, medical records review provides for accurate medico-legal documents.

The QUALITY ASSURANCE GUIDE states that the medical records review function is performed at a minimum by the medical staff in cooperation with the nursing department or service, the patient administration department, and representatives or other departments as appropriate. The medical records review must ensure that each medical record or representative sample of records reflects the diagnosis, results or diagnostic tests, therapy rendered, condition and in-hospital progress of the patient, and the condition of the patient at discharge. Additionally it is required that a statistical review regarding the timely completion of all medical records be conducted. The medical record review function should determine or make recommendations regarding the format of the medical record, the local form used in the medical record, and the use of electronic data processing and storage systems for medical record purposes. Finally, the medical records review function is required to maintain written reports of conclusions, recommendations, and actions taken, and the results of the actions taken are maintained.

The instruction requires that the review function be performed by a medical record review committee (or by a committee that performs related functions such as utilization review). Specifically, the medical staff is required to review records for clinical pertinence, timely completion,

proper format, and use of authorized forms. The basic requirements are:

(1) Medical records are assessed for their overall adequacy for use in quality assessment activities.

(2) Course of the patient's medical evaluation, treatment, and condition changes are clearly stated.

(3) Medical record is adequate in describing provisions for continuity of patient care, whether related to evaluation or treatment.

(4) Medical records are assessed for their usefulness in protecting the legal interest of the patient, the practitioner, and the hospital.

(5) There is evidence of communication between the responsible practitioner and other health professionals contributing to a patient's care.

(6) Determinations are made concering the medical record format and format of all forms used in the record; use of microfilm; and compliance with the Manual of the Medical Department.

(7) Review and evaluation of preprinted standing orders.

(8) Timeliness and completeness of medical record information are evaluated. [Ref. 43]

The QUALITY ASSURANCE GUIDE also requires specific nursing service functions with regard to medical records review. The nursing service is required to review the medical record for timeliness, adequacy, and quality of nursing care.

The patient administration department must provide the medical staff with information and reports to aid the timely completion of medical records. It should provide those responsible for the overall medical review with at least the following statistical information, monthly:

(1) Number of delinquent records for missing histories and physicals, operative reports, discharge summaries, etc.

(2) Number of operating reports without required informed consent.

(3) Number of records without patient identification throughout.

(4) Code number of providers using nonapproved abbreviations.

(5) Code number of providers whose penmanship is illegible.

(6) Code number of providers not authenticating verbal orders after 24 hours.

(7) Number of records with missing consultation reports.

(8) Number of records with missing laboratory or X-ray reports.

(9) Number of records with entries not dated or authenticated by responsible practitioners. [Ref. 44]

The instruction also addresses efforts to overcome JCAH contigencies for delinquent medical records. Delinquent medical records are those records that are not completed within the time period following patient discharge in accordance with the medical staff bylaws, rules and regulations.

As a plan of action for conducting a records review, the QUALITY ASSURANCE GUIDE recommends developing a system or mechanisms that require:

(1) Each committee member review the medical record as a medico-legal document that may require defense in a court of law.

(2) Each committee member review the medical record as if they must assume the full care of the patient with only the medical record as the sole source of past treatment.

(3) Each doctor or nurse, in reviewing medical records, should standardize their approach by formulating consistent responses to the following questions:

(a) What has been done for the patient?
(b) What should I look for?
(c) How has the patient responded?
(d) How do I measure what was done?
(e) What is going to be done next?
(f) Does the medical record reflect the quality of care provided? [Ref. 45]

In summary, most common JCAH recommendations for medical record review are primarily medical staff responsibility. A standard criterion for medical record keeping is

> Keep the record in such fashion that if all the practitioners treating a patient were suddenly to disappear, a new team coming on the scene could, from the record alone, immediately continue the best possible treatment. [Ref. 46]

j. Chapter 10. Antibiotic Clinical Usage Review

Chapter 10 of Section B describes the medical staff antibiotic clinical usage review function requirement. Reviews are conducted to evaluate the consistently large number of prescriptions written in acute care facilities for antibiotics, and the potential dangers to patients receiving antibiotics, which may be life threatening.

The instruction states that a plan of action must be developed for a comprehensive program integrated with infection control, pharmacy and therapeutics committee, infection surveillance officer, laboratory and individual nursing units such as ambulatory care and emergency room, and the medical record department. Specific requirements for antibiotic clinical usage review include the following:

(1) Antibiotic usage review shall be a medical staff function.

(2) The review method is determined by the medical staff.

(3) The review must be a clinical review and not just a statistical or prevalence study.

(4) The medical staff shall review the appropriateness, safety, and effectiveness of the prophylactic, empiric, and therapeutic use for all types of antibiotics used.

(5) The review shall be conducted regularly.

(6) The review shall be a biphasic process consisting of:

(a) Ongoing monitoring of antibiotic usage by all departments and clinics.
(b) Problem and opportunity identification to improve the quality of care.

(7) Use of screening mechanisms to identify the problems of a specific antibiotic, or category of antibiotics, for more intensive evaluation.

(8) Use clinically valid criteria in the screening process and for more intensive evaluation of known or suspected antibiotic usage problems.

(9) Written reports of conclusions, recommendations, actions taken, and the results of actions taken are maintained and reported at least quarterly. The infection control committee is informed or consulted as appropriate. [Ref. 47]

An adequate antibiotic utilization review process will include a medical staff-directed ongoing review of the use of antibiotics including the prophylactic use of antibiotics by in-patients, hospital-sponsored ambulatory care patients, and emergency care patients. [Ref. 48]

k. Chapter 11. Support Services Requiring Medical Staff Direction

Chapter eleven of Section B addresses support services requiring medical staff direction which are listed as follows:

(1) Ambulatory care services.

(2) Anesthesia services.

(3) Emergency care services.

(4) Nuclear medicine services.

(5) Pathology or medical care services.

(6) Radiology services.

(7) Respiratory care services.

(8) Special care services.

Regardless of the support services, all physician heads have similar functions and responsibilities. According to the instruction they must ensure the quality, safety, and appropriateness of patient care provided they are monitored and evaluated on a regular basis and that appropriate actions based on results are taken. Additionally, they must actively participate in criteria development (Preestablished occurrence screening criteria will permit nonphysician staff to identify clinical problem areas). [Ref. 49]

1. Chapter 12. Medical Staff Participation in Facility-Wide QA Functions

Chapter twelve, the final chapter of Section B, discusses medical staff participation in the facility-wide QA program. The medical staff is required to participate in the following facility-wide multidisciplinary activities:

(1) Infection control committee program.

(2) Safety committee or safety program.

(3) Disaster planning.

(4) Utilization review program.

The medical staff bylaws of a facility should contain statements of purpose, objectives, and functions

pertaining to medical staff participation in the above-mentioned facility-wide activities. [Ref. 50]

3. Section C--Support Services (Ancillary Departments) QA Functions and Activities

a. Chapter 1. Overview

The first chapter of Section C provides guidelines that enable the staff of each support service (ancillary department) to:

(1) Become knowledgeable of its own quality assurance activities.

(2) Systematically review, evaluate, and monitor the quality and appropriateness of care being provided as an ongoing and intrinsic part of the daily operation of each ancillary department.

(3) Resolve problems at the lowest level (assumption that staff knows best what the problems are and should want a voice in determining the resolution).

(4) Establish mechanisms for communicating problems that cannot be solved at the lowest level up the chain of command.

(5) Coordinate and integrate departmental quality assurance activities into the command-wide QA program.

(6) Develop an individualized QA plan that complements the facility-wide QA plan and enables each service to conduct QA activities in similar ways. [Ref. 51]

The following is a listing of the scope and frequency of the review and evaluation of the quality and appropriateness of patient care and patient care services provided by support services.

RESPONSIBILITY	SUPPORT SERVICE	FREQUENCY
Physician-Head	Anesthesia Services	Monthly
	Emergency Services	Monthly
	Nuclear Medicine Services	Quarterly
	Pathology and Medical Laboratory Services	Quarterly
	Radiology Services	Quarterly
	Respiratory Care Services	Quarterly
	Special Care Unit(s)--Multidisciplinary Committee Required	Quarterly
Head of Department with Medical Staff Input	Dietetic Services	Annual
	Pharmacy Services	Quarterly
	Rehabilitation Services	Quarterly
	Hospital-Sponsored Ambulatory Care Services--Multidisciplinary Committee Required	Semi-Annual
Directorate	Nursing Services	Quarterly
Head	Social Work Services	Semi-Annual

[Ref. 52]

The department head is responsible for effective implementation of quality assurance mechanisms which are designed to identify and resolve high priority patient care problems. Problems are identified through multiple data sources, including departmental monitoring activities and interaction among department and service members regarding problems encountered in providing direct patient care. Criteria that reflect best available current clinical knowledge

and skills are used in the department or service's monitoring, evaluation, and problem-solving activities.

According to the QUALITY ASSURANCE GUIDE, monitoring, evaluation, and problem-solving activities of a department are:

(1) Integrated with the hospital's overall QA program.

(2) Compatible with all applicable rules and regulations.

(3) Documented.

The instruction further states that review, evaluation, and monitoring of patient care are an ongoing, planned, systematic process thorugh which opportunities to improve care as well as important problems in patient care are identified, resolved, and reported. [Ref. 53]

MTF's are complex organizations in which patient care results depend upon the interrelated contributions of a variety of health care professionals. The support services, like all others, are accountable, through the hospital's overall QA program, for the effectiveness and efficiency of its patient care services, including the resolutionof discovered problems.

The review and evaluation conducted by the support services should result in the identification of needs for policy decisions, changes in behavior, staff and patient education, changes in systems and procedures, changes in clinical privileges delineation, budget changes, etc. The goal is not only the establishment of a uniform level of high

quality care, but also the provision of services that are appropriate to the needs of patients served.

Directorates for ancillary services are responsible for the overall quality of patient care and the quality of the patient care services provided by their departments. They, in turn, delegate responsibilities to the head of each department.

It is the responsibility of the head of each department to assure that the review and evaluation is conducted. For example, the head of the operating room nursing department is responsible for the review and evaluation of departmental nursing care, and the head of social work department and the head of food management (dietary) are responsible for evaluation of care provided in their departments.

Physician heads of ancillary departments are responsible for conducting the review and evaluation. In emergency care services, hospital-sponsored ambulatory care services, and special care units, the review and evaluation is to include care provided by physicians as well as care provided by nurses and other health care providers.

In small, nondepartmentalized facilities, it can be the total medical staff's responsibility to oversee review and evaluations of the services where a physician head is not assigned. If the services (i.e., respiratory care, physical therapy, social service or other types of therapy) are provided, although no formal departments exist,

these services must be reviewed at specified intervals by the medical staff.

Patient care support services not specifically mentioned in the instruction are required to be reviewed at least annually under the direction of the head of the respective department (example: EKG service, immunization service, etc.). [Ref. 54]

b. Chapter 2. Departmental Unit QA Plan

Chapter two of Section C states that the most important single element in QA is that each support service assess itself and change its procedures to maximize its effectiveness. The instruction further states that this can only be done within each ancillary department, by staff members who are familiar and professionally involved with the problems, and who become personally committed to resolving problems. The QA program in any facility will always be the sum of its parts, and will be good only to the extent that each part is good. A central authority, such as a QA coordinator, is useful in helping individual departments to become more effective, but can never be a substitute for individualized department level QA activities. [Ref. 55]

The QUALITY ASSURANCE GUIDE requires each department and clinic to have a written QA plan for its internal quality assurance program. This document shall inform department staff:

(1) How their departmental QA activities fit into the overall command-wide QA program.

(2) How responsible individuals are to be formally educated and by whom to ensure that they understand what is expected and the scope of their responsibilities.

The head of each department must assign a qualified staff member the collateral assignment to conduct QA activities for the department.

According to the instruction, each facility must establish a task force comprised of individuals who have been assigned the collateral responsibility for coordinating QA activities within their respective departments, and other leaders within the department or clinic to discuss and develop a step-by-step process for the production of a standardized format for a written unit QA plan. It is recommended that the directorate for ancillary services be appointed as chairperson. The instruction suggests utilizing Section A of the QUALITY ASSURANCE GUIDE as a reference for development of a QA plan format. [Ref. 56]

The instruction requires each support service to develop guidelines for a support service unit QA plan consisting of the following:

(1) HOW problems will be identified

- (a) Departmental meetings?
- (b) Utilization review of resources?
- (c) Complaints?
- (d) Patient and staff surveys?
- (e) Continuous monitoring?
  - [1] Written standards of care?
  - [2] Complications?--Occurrence screening criteria?
- (f) Other sources?
  - [1] Staff and patient injury reports?
  - [2] Infection surveillance reports?
  - [3] Equipment failures?

(2) WHO will be responsible for

(a) Ensuring problems are identified?
(b) Proposing solutions?
(c) Implementing solutions, if possible?
(d) Referring problems whose solutions cannot be implemented to appropriate resource?
(e) Monitoring to resolution?
(f) Reporting to quality assurance committee (QAC)?
(g) Receiving reports from QAC?
(h) Acting upon reports from QAC?

(3) WHEN will

(a) Problems be identified?
(b) Actions be taken upon problems (prioritization)?
(c) Reports be submitted to the QAC?
(d) Evaluation of the QA activity be done?

(4) WHEN records will be maintained

(a) Problem summary reports (PSRs)?
(b) Status reports of problems?
(c) Problem referral reports (PRRs)?
(d) Departmental meeting minutes?
(e) Performance/credential appraisal records?
(f) QA related education programs?

(5) WHEN/HOW/WHO will evaluate the overall effectiveness of the departmental QA program

(a) Mechanisms to be used?
(b) Frequency? [Ref. 57]

c. Chapter 3. Use of Screening Criteria by Support Services

Chapter three of Section C describes use of screening criteria by support services, as such criteria can lead to the efficient discovery of problems. The instruction states that each patient care area should develop this problem-finding method and establish a list of screening criteria that automatically triggers a review. These criteria should be based on accepted standards of practice and established policies and procedures so they can be easily written by each

department without external assistance. The screening criteria selected should be clearly stated and stand by themselves without multiple exceptions having to be recognized. [Ref. 58]

4. Section D--Free-Standing Ambulatory Care QA Program

a. Chapter 1. Introduction

The first chapter of Section D promulgates requirements that all free-standing clinics establish a QA program based on available resources and level of care provided. Although this section specifically addresses free-standing medical ambulatory clinics, the instruction states that the concepts described are also applicable to dental free-standing clinics.

Ambulatory care refers to care of patients not hospitalized. The movement to decrease hospital cost through expansion of ambulatory one day surgery programs and the philosophical shift toward keeping patients out of an inpatient setting unless absolutely necessary are increasing the number of outpatients who would previously have been admitted to inpatient facilities.

Because ambulatory patient care evaluation methods are currently in a neophyte stage, analysis of the nature of ambulatory care must be conducted to identify the major difference between the inpatient and outpatient setting. The instruction recommends developing conceptual models for patient

care evaluation systems that are unique to free-standing ambulatory care facilities. [Ref. 59]

A quality assurance program in a free-standing ambulatory care facility must analyze the way in which care is delivered and have access to all currently available data sources. Ambulatory care is preventive and anticipatory and requires more agreement between patient and provider about problems and proposed treatment. Patients enter and leave ambulatory care clinics with relative ease; consequently the prescribed therapy cannot be observed, reviewed, and evaluated as easily as for inpatients. [Ref. 60]

b. Chapter 2. Organization of QA Program for Ambulatory Care

Chapter two of Section D provides an overview of the components, methodology, and manpower required to develop a systematic approach to the organization of a QA Program for Ambulatory Care. The QUALITY ASSURANCE GUIDE suggests that most staff in ambulatory care facilities find it difficult to implement problem-focused activities because of the lack of a data base or monitoring system and because their patient population is fluid.

In developing a QA program, the instruction states that the staff of the ambulatory care facilities can use the same principles of problem-solving that are used in hospital settings. Although the medical record (the document-based review method) remains the primary approach for problem identification, the methods of observation studies, staff and

patient surveys, and interviews can and should be routinely utilized in the ambulatory care setting. Likewise, other multiple data sources are to be used in problem identification. [Ref. 61]

In developing a QA program for ambulatory care, the QUALITY ASSURANCE GUIDE suggests that each clinic utilize the JCAH Free-Standing Ambulatory Care Standards as measuring stick for achieving optimal levels of care, and developing a QA program, reflective of its resources. The required elements of a QA program for ambulatory care are as follows:

(1) The commanding officer or officer in charge has overall responsibility for the quality of patient care provided in the organization.

(2) The command strives to assure high quality patient care through the establishment, maintenance, and support of an effective command-wide quality assurance program.

(3) Administrative and clinical staffs of clinics implement the command's quality assurance program and report information to the commanding officer.

(4) A written plan for the quality assurance program describes the program's objectives, organization, processes for monitoring and evaluating the quality of patient care, and mechanisms for overseeing the effectiveness of the monitoring, evaluation, and problem-solving activities.

(5) The scope of the quality assurance program should include at a minimum, the specifically required elements of the inpatient program.

(6) Documentation and, as appropriate, the reporting of the action(s) taken and the effectiveness of such action(s).

(7) There are to be mechanisms designed to oversee and assure the appropriateness and effectiveness of any

monitoring, evaluation, and problem solving activities performed by departments, services, or committees. Additionally, appropriate information is to be shared when problems or opportunities to improve patient care involve more than one department or service, and adequate followup on the status of identified problems must occur.

(8) The objectives, organization, and effectiveness of the quality assurance program are evaluated at least annually and revised as necessary. [Ref. 62]

The QUALITY ASSURANCE GUIDE states that the following review process parameters for the ambulatory care QA program need to be continuously evaluated:

(1) Availability and accessibility of health services.

(2) The intake system for patients during and after normal hours of operation.

(3) The availability of emergency and after-hours care.

(4) A mechanism for informing patients of the names, professions, and titles of the professionals providing and/or responsible for their care.

(5) The use of appropriate diagnostic procedures.

(6) Treatment that is consistent with the clinical impression or working diagnosis.

(7) The availability and use of appropriate consultation.

(8) Appropriate, accurate, and complete medical record entries.

(9) Patient instruction and education regarding the treatment program, including the use of medications and therapies.

(10) Adequate transfer of information when patients are transferred to or from other health care providers, within and outside the organization.

(11) Evidence of continuity of care.

(12) Reasonable followup regarding patient adherence to treatment.

(13) Professional staff practice in an ethical and legal manner.

(14) Concern for the cost of care demonstrated by the relevance of health care services to the needs of the patients; the absence of duplicative diagnostic procedures; the appropriateness of treatment frequency.

(15) The use of the least expensive alternative resources when suitable. [Ref. 63]

While the QA program for ambulatory care is similar in many respects to the hospital QA program, the following differences were noted during review of the QUALITY ASSURANCE GUIDE:

(1) The quality assurance coordinator position can be part-time.

(2) In free-standing clinics, infection control and safety functions should be assigned to an individual vice a committee with problems reported to heads of departments, directorates, or the QA committee as appropriate. Likewise antibiotic, drug utilization reviews, and surgical case reviews can be performed by individual physicians who report findings to the total medical staff.

(3) QA committee functions can be performed as an additional responsibility of the commanding officer's meeting of the directorates.

(4) A separate QA committee is not required. For medical and dental clinics, the QA committee functions can be included in existing monthly senior management staff meetings conducted by the commanding officer.

(5) Since the QA coordinator position may be part-time, a medical library committee is to be established to maintain an up-to-date collection of references pertinent to quality assurance. Membership of the committee is to be multidisciplinary and have representation of at least medical staff, nursing service, administration, individual(s) trained to manage the library, and others as appropriate.

(6) Since the QA coordinator position may be part-time, an education committee is to be established to provide continuing staff education relative to QA activities.

The membership shall be multidisciplinary and limited to 5 or 6 members. The directorate of administrative services and the head of staff education and training department shall be members. There is to be medical and nursing services staff representation.

(7) The directorate of the medical services should be considered for the collateral position as physician QA advisor.

(8) Individual physicians can perform QA functions vice a committee. For example, an appointed physician, with the assistance of the pharmacy and laboratory staff, using approved preestablished criteria can be responsible for documenting and reporting findings and recommended actions of the drug and antibiotic usage reviews.

(9) Individual nursing service staff members who are responsible for performing specific clinical functions or in charge of specific clinical areas should be also responsible for performing related QA activities (i.e., nursing personnel in charge of Central Sterile Supply Service should conduct review and report problems).

In accordance with NAVMEDCOMINST 5450.1, commanding officers of naval medical and dental clinics are charged with the responsibility for the complete operation of branch clinics that come under their purview. The instruction states that quality assurance programs for branch clinics should be limited and controlled by their available resources and the services provided. Commanding officers of hospitals and dental facilities are to provide branch clinics with expert assistance to modify their QA programs to fit their needs, and are responsible for the ongoing monitoring and evaluation of the efficiency and effectiveness of these programs. Heads and officers in charge of branch clinics are to be delegated the responsibility for the establishment and implementation of the QA program. [Ref. 64]

c. Chapter 3. Ambulatory Care Medical Record Review Process

Chapter three of Section D describes the ambulatory care medical records review process. The medical records of patients receiving treatment in an ambulatory setting commonly reflect care delivered over a period of years. The medical record is a primary data source for evaluating quality and appropriateness of ambulatory care. Yet, it is frequently discovered that many things are said but not recorded. The medical record should reflect the care provided. The medical record in the ambulatory care setting has a dual role: (1) to give providers a patient history, informing them of previous illnesses and treatment; and (2) to serve as the major vehicle used in patient care evaluation. To accomplish these objectives, the QUALITY ASSURANCE GUIDE states that there must be:

(1) Standardization so that patient medical records can be easily analyzed (accomplished by implementation and enforcement of written policies and procedures for documenting in medical records).

(2) Summarization of inpatient record entries that provide for a coordinated, comprehensive analysis of care. This can be accomplished with the use of the Problem Summary List NAVMED 6150/20.

The instruction states that the command must set standards regarding the quality, quantity and format of medical record documentation. The instruction further states that information in the medical record must include at least the following data: patient identification; diagnostic and therapeutic orders; clinical observations including treatment results; procedures and test results; patient disposition

and any pertinent instructions given to the patient or family for follow-up care; immunization record; allergy history; growth charts for pediatric patients; preoperative, perioperative, postoperative surgical and anesthesia care; and information about referrals to and from outside facilities and agencies. [Ref. 65]

d. Chapter 4. Problem Identification in Ambulatory Care Setting

Chapter four, the final chapter Section D, describes problem identification in the ambulatory care setting. The instruction states that multiple data sources should be used to identify major problems that have a high impact on patient care, rather than only those that will be convenient to assess. The instruction suggests the types of problems that can be identified and studied as to cause are:

(1) Chronic problems not written on the problem summary list (NAVMED 6150/20) including allergies.

(2) Lack of continuity of care.

(3) Data base not current in medical record of patients with chronic health problems.

(4) Inadequate phone access, especially complaints of too many holds.

(5) Excessive utilization of medical care for nonsignificant illness.

(6) Progress notes hard to read.

(7) Notes missing--no record of visit.

(8) Chart not available at time of visit.

(9) Referring physician or facility communication inadequate.

(10) No feedback from consulting physician. [Ref. 66]

The instruction recommends a list of occurrence screening criteria be developed and approved which will trigger an automatic reporting and review process if an occurrence happens. Such can be used by all disciplines and problems identified that are likely to have significant impact.

The QUALITY ASSURANCE GUIDE specifically addresses ambulatory surgery. JCAH standards apply primarily to any surgical procedure that requires supplemental local (e.g., an intravenous sedative administered with local anesthesia), regional, spinal, or general anesthesia. The instruction states that when ambulatory surgical and anesthesia services are provided by a facility, the policies, procedures, and environmental conditions should be consistent with those applicable to inpatient surgery, anesthesia, and postoperative recovery found in the JCAH Ambulatory Health Care Standards Manual. [Ref. 67]

The QUALITY ASSURANCE GUIDE states that none of the quality assurance monitoring requirements can stand alone; there must be an interrelationship between activities. Methods of communicating and documenting need to promote the orderly flow of information that will reach all levels of staff. The ambulatory care QA program must be a three-phase effort (review and evaluate, identify problems, solve problems) to determine the present status of health care delivery and to improve it wherever and whenever appropriate at a reasonable cost. [Ref. 68]

5. Section E--QA Programs for Free-Standing Dental Clinics

a. Chapter 1. Introduction

Chapter one discusses the requirements for all free-standing dental clinics to establish a QA program based on available resources. A free-standing dental clinic is defined as any dental treatment facility that is not a hospital dental service or department. The QUALITY ASSURANCE GUIDE states that all guidelines and formats in the instruction may be modified to reflect dental quality assurance needs.

Historically, naval hospital dental services have been governed by American Dental Association (ADA) Standards for Hospital Dental Services, in conjunction with JCAH standards. Other dental treatment facilities have not been governed by any formal QA standard. With these differences in mind, conceptual models need to be developed for patient care evaluation systems that are unique in free-standing dental care facilities. [Ref. 69]

b. Chapter 2. Organization of QA Program

Chapter two of Section E provides an overview of the organization required to develop a comprehensive problem-focused dental QA program. Dental care facilities find it difficult to implement problem-focused activities because of the lack of a data base or monitoring system. In developing a QA program, the instruction suggests dental clinics use the same principles of problem-solving used in hospital settings. The instruction further states that although the

dental record remains the primary source for problem identification, other methods including observation studies, surveys, and interviews should also be used.

There are no accreditation requirements for free-standing dental clinics. Each clinic, however, is required by the QUALITY ASSURANCE GUIDE to utilize the ADA STANDARDS FOR HOSPITAL DENTAL SERVICES as a guideline to develop a QA program reflective of its resources.

The instruction states that the commanding officer or officer-in-charge has overall responsibility for the quality of outpatient dental care. The QUALITY ASSURANCE GUIDE further states that a plan shall be written describing the objectives, organization, and mechanisms for evaluating the outpatient dental care quality assurance program. As is the case with hospitals, the QUALITY ASSURANCE GUIDE requires that a QA coordinator be assigned. The following three committees are recommended by the instruction during the organization of a QA program for outpatient dental care:

(1) Dental Records Review Committee

(2) Medical Library Committee

(3) Education Committee. [Ref. 70]

The director of dental clinic administration is required to chair monthly staff meetings, distribute agendas for the monthly meetings, and delegate responsibility for linen handling, housekeeping, dental records review, and safety and preventive maintenance.

The instruction requires that a calendar be developed, the timeliness monitored, and minutes filed for the following meetings:

(1) QA Committee--Monthly

(2) Credentials Review Committee--As often as necessary

(3) Dental Staff QA Briefing--Monthly

(4) Dental Record Review Committee--Monthly

(5) Medical Library Committee--Twice a year

(6) Education Committee--Quarterly. [Ref. 71]

c. Chapter 3. Dental Records Review Process

Chapter three provides guidance for the dental records review process. The dental records of patients reflect care delivered over a period of years. Since the dental record is the primary data source for evaluating dental care, the dental record should reflect the care provided and serve as the major vehicle used in patient care evaluation.

The QUALITY ASSURANCE GUIDE requires establishment of a dental records review committee with a dental officer appointed as chairman. The actual statistical records surveys may be performed by a dental technician and reviewed by the committee. However, the committee is required to meet monthly to discuss problems detected by the records review. The committee's responsibility is to conduct record reviews and prepare a summary report. [Ref. 72]

d. Chapter 4. Problem Identification in Dental Clinics

Chapter four, the final chapter of Section E, presents a matrix to be utilized for problem identification

in dental clinics. Problems which may be identified with the use of this matrix are:

(1) Chronic problems.

(2) Lack of continuity of care.

(3) Dental Health Questionnaire not current.

(4) No record of visit.

(5) Referring health care provider communication inadequate.

(6) No feedback from consulting health care provider. [Ref. 73]

As a conclusion to Section E, the instruction suggests that a quality assurance program in a free-standing dental care facility must analyze the way in wyich care is delivered. The program must be preventive, anticipatory, and requires more agreement between patient and provider about proposed treatment.

6. Section F--Integration of Risk Management and Utilization Review into the QA Program

Section F, the final section in the QUALITY ASSURANCE GUIDE, addresses the requirement that all naval medical and dental treatment facilities incorporate the risk management (RM) function as a component of their QA program. In addition, it requires each facility to establish an Incident Reporting System that productively detects actual and potential problems; prevents the chance of harm to patients, visitors, or staff members, and financial loss to the facility; and that can be used as an indicator that the facility provides the highest quality of care possible.

a. Chapter 1. Risk Management Functions

Chapter one of Section F provides the background and rationale for establishment of the risk management functions. Until the malpractice insurance crises of the mid-1970's, the integration of risk control authority, accountability, and communication of corrective action was, in many instances, a splinter activity within the health care delivery system. In some facilities today, it still remains that way.

Risk management is being widely discussed, yet its application in the health care setting is frequently misunderstood. As long as risk management is viewed as an activity distinctly separate from existing quality assurance programs, all attempts will meet with limited success. Unfortunately, many existing risk management programs deal primarily with custodial liability (focus on environmental hazards) rather than the deficiencies in medical care. They fail to deal with the critical areas of provider-related incidents.

The instruction states that cases of custodial negligence are usually minor and lead to minimal dollar liability, and usually such claims are settled out of court. More importantly, custodial negligence is separate and distinct from professional negligence. The risk of professional negligence is usually shared by both physician and hospital, and is accompanied by greater potential for larger claims and settlements. Nationally, the leading allegations in malpractice claims are related to surgery and birth-related problems. The specialists most frequently used are surgeons

(20.7 percent), obsetetricians/gynecologists (21.8 percent), general practitioners (12.3 percent), orthopedists (7.7 percent), and internists (4.6 percent). An analysis of alleged malpractice cases filed against the Navy displays similar percentages and patterns.

The instruction states that the effectiveness of risk management efforts depend heavily on the individual staff member's perception of its purpose and their motivation to participate. The physician's participation in risk detection activities and incident reporting is the key to control loss and liability prevention. A risk management system that is self-directed and self-motivated by the medical staff will be more effective than one that is externally engineered and imposed. More can be accomplished if the medical staff acts as the motivators rather than the motivated for quality, patient safety, and liability control. [Ref. 74]

In providing a rationale for establishing the risk management function as an integral part of the facility-wide QA program, the QUALITY ASSURANCE GUIDE further states that coordination of the quality assurance functions with the risk management function will utilize the expertise of the medical staff and other health care providers. Such will create a unified facility-wide system intended to detect and prevent deviations from expected patient outcome.

The instruction addresses the fact that risk detection activities cannot be conducted in isolation from day-to-day problem identification methods in clinical areas.

If problems are to be solved at the lowest level and if support and clinical departments are to establish effective unit QA programs, each department must be risk management oriented. Furthermore, each department must integrate the risk management function within its total QA activities with the same level of importance as the interfacing of safety, infection control, utilization review, preventive maintenance program, etc.

The QUALITY ASSURANCE GUIDE provides examples of the reasons for failure of the risk management function:

(1) The risk management effort is fragmented and narrowly defined, and consists primarily of filing incident reports.

(2) Important clinical problems are rarely reported on incident forms.

(3) Channels of communication are not established between risk management personnel and other health professional involved in the review.

(4) Risk coordinators are unable to get the "right" information.

(5) Risk management activities are isolated from day-to-day problems in clinical care.

(6) The program lacks clinical staff support and participation. [Ref. 75]

Additional reasons for RM integration into the QA program are:

(1) Comparable goals--both QA and RM strive to ensure that optimal patient care is maintained and delivered in a safe environment.

(2) Areas of overlap in the relationship between QA and RM; both:

(a) Identify serious adverse patient events.
(b) Use the same data sources and analysis methods.
(c) Study patient care problems.
(d) Resolve problems through education and changes in policy and procedure.
(e) Have the same staff members involved: physicians, nurses, administrators, other health professionals. [Ref. 76]

The QUALITY ASSURANCE GUIDE provides the following as overall objectives of an integrated risk management system:

(1) To place risk management responsibility in a prominent position in the organizational structure.

(2) To widely communicate the purpose and efforts of the risk management function.

(3) To ensure the staff's commitment to risk management efforts is not based solely on the fear of lawsuits, but on the dedication to providing the highest possible standard of care.

(4) To develop an incident reporting system as a tool for implementing, monitoring, and evaluating the risk management activities.

(5) To identify and correct problems before a patient, visitor, or staff member is harmed and to ensure the highest quality of care possible. [Ref. 77]

The QUALITY ASSURANCE GUIDE describes the basic functions of the risk management system as including at least the following:

(1) Protect financial assets of the hospital.

(2) Protect human and intangible resources.

(3) Prevent injury to patient, visitors, employees, and property.

(4) Reduce loss: focusing on individual loss or on single incidents.

(5) Prevent loss: to prevent incidents by improving the quality of care through continuing and ongoing monitoring.

(6) Review each incident and the patterns of incidents through the application of the steps in the risk management process: risk identification, risk analysis, risk evaluation, and risk treatment. [Ref. 78]

The QUALITY ASSURANCE GUIDE defines risk as a situation, occurrence, or a course of action that involves an element of danger, peril, hazard, or loss; the chance of losing financial assets or the chance of loss by incurring liability for injury to persons. Liability is defined as the state of being bound or obliged by law to assume responsibility for the consequences of one's personal or professional behavior.

The instruction more specifically addresses the types of liability with regard to risk management as being the following:

(1) Professional liability. The obligation to assume responsibility for the consequences of professional behavior that adversely affects a patient's condition or outcome. Among those health professionals with potential for such liability are physicians, nurses, respiratory and physical therapists, parmacists, etc., i.e., all those involved in patient care and treatment. The facility could be held liable for the acts of its employees. Professional negligence falls into three categories.

(a) Unprofessional and unethical conduct. Health care personnel behave in an unprofessional or unethical manner as determined by professional association standards or other measures of an acceptable code of conduct.

(b) Unreasonable lack of skill. Professionals are expected to possess a reasonable level of skill and training.

(c) Deviation from professional standards and facility's policies and procedures. Health care personnel are expected to meet established standards in the delivery of patient care.

Liability may be incurred when a clinician fails to follow the facility's own standard as set forth in bylaws and in clinical policies and procedures.

(2) General and custodial liability. Liability unrelated to direct treatment; general liability is that legal responsibility which a facility might incur when harm befalls a patient, visitor or staff member as a result of actions unrelated to direct medical treatment. Frequently, it is impossible to determine whether harm has resulted from the neglect of clinical responsibility or the neglect of custodial responsibility; for example, did the nurse fail to raise the bed rail or was the bed rail defective?

(3) Corporate professional liability. The obligation that the facility, as an organization, may have to assume for a deviation from professional standards. For example, a facility has a responsibility to ensure that the clinical staff is adequately trained and periodically evaluated. A facility may be negligent if it does not assess compliance to its own policies and procedures and ensure that such policies and procedures are enforced. A facility may also be liable if it fails to establish, assess, improve, and monitor standards of patient care delivery. [Ref. 79]

The instruction defines the major factors that affect the successful implementation of a risk detection and risk control system as staff education, organizational structure, competency of assigned personnel, and establishment of an incident reporting system. The instruction further states that staff education should encompass all levels of staff and be conducted on a regular basis, including an orientation program for new personnel.

The QUALITY ASSURANCE GUIDE, while discussing organizational structure, states that the risk management system must be tailored to fit the individual facility. It further states that the system must be designed in light of

the resources available, the claims history of the institution, the high risk issues occurring, and the number of hazardous work areas, etc. Moreover, a system that looks good on paper is doomed to fail unless the entire health care team understands, supports and has access to the system. Risk detection and risk control must become everybody's business.

The QUALITY ASSURANCE GUIDE requires that the organizational structure of the risk management function and the incident reporting system be consistent with the organizational structure of the command-wide QA program. Regardless of the organizational structure, the commanding officer is ultimately responsible for the risk management function.

The executive officer, as manager of the command-wide QA program, is automatically accountable for the risk management component of the overall program, and is directly responsible for the coordination and monitoring of command-wide risk management activities. He is also responsible for establishing, implementing, monitoring, and protecting the confidentiality of privileged information of the command's incident reporting system.

The command QA coordinator is required to monitor the resolutions of risk management problems throughout the command at the same level of interest as all other QA activities. Additionally, a risk coordinator must be appointed by the commanding officer to act as a special assistant to the executive officer in matters relevant to coordinating

and integrating the risk detection and risk control activities, and to assist the executive officer in the establishment of an effective incident reporting system.

The QUALITY ASSURANCE GUIDE states that single administrative responsibility is preferable and recommended vice a risk management committee. The instruction suggests that one qualified person, with the support of a productive safety committee, would be more effective for the authority, accountability, responsibility, communication of risks, and the monitoring of corrective actions.

As an optional organizational model for large facilities with a QA unit administered by a physician QA head, the physician head may be made responsible for risk management activities. This person has responsibility for the incident reporting system and filing of risk-related information. Under this option, the risk management coordinator would be assigned as a staff member of the QA unit and be responsible to the physician QA head. [Ref. 80]

The instruction requires that commanding officer's of those facilities that do not have a JAG officer on the staff formally request the area Naval Legal Services Office (NLSO) assign a JAG officer to participate in risk management (RM) activities and attend regular meetings. Furthermore, whether a full-time or part-time member of the facility staff, the legal officer is expected to devote considerable time to risk management issues in the performance of investigation

and representation in malpractice litigation, prevention of lawsuits, and education of staff.

A legal officer familiar with the routine of the command can protect the interests of the command and the patients by recommending: (1) revisions in administrative and clerical procedures and policies; (2) methods to improve documentation of patient care; and (3) methods to protect patients rights. [Ref. 81]

As an additional component of the risk management program, the QUALITY ASSURANCE GUIDE requires that the commanding officer appoint a command patient contact representative who is responsible for the establishment and management of the patient contact program. The instruction suggests that the patient contact program can be very effective in reducing malpractice litigation.

The patient contact representative functions in the role of neutral mediator and can deal with problems that range from complaints about careless housekeeping to far more serious concerns about medical treatment. The patient contact representative receives notice of all patient complaints, investigates causes, and ensures patient satisfaction. Additionally, the representative is required to ensure that incident reports are initiated (when required) and that the reports are routed, as required, to the commanding officer via the executive officer for final investigative action.

An important requirement of the patient contact representative's job is to analyze and evaluate the findings

of patient satisfaction surveys at least semiannually. The representative is required to prepare a written report of the aforementioned analysis of patient satisfaction surveys. These reports are then submitted to the commanding officer via the executive officer and the executive committee of the medical staff or QA committee (whichever is appropriate) for recommended corrective action. Additionally, this information is submitted to the geographic naval medical command. [Ref. 82]

The QUALITY ASSURANCE GUIDE defines an incident as an individual episode of harm or potential harm or serious expression of dissatisfaction by patients, visitors, and staff. Within the naval medical and dental treatment facilities, the instruction requires that the incident report be the primary element in the basis of risk control and safety programs systems for identifying potential risk situations, minimizing their severity, and for preventing their recurrence.

All risk management approaches focus on the occurrence of an event that is inconsistent with the desired patient outcome. To the individual medical or dental treatment facility, these events are generally known as patient or staff incidents. The circumstances surrounding these incidents require the completion of an incident report for subsequent review and action.

Traditionally, the information collected on these reports is usually a narrative description of the incident. The information provided is often not specific enough to be

measurable, and thus can be interpreted differently by staff, committees, departments, etc. Often persons who review the incident reports are unable to review all of them, thus precluding a comprehensive perspective of incident occurrences. Consequently, each naval medical or dental treatment facility is required to maintain incident reports that describe an incident objectively. [Ref. 83]

The instruction states that the importance of maintaining incident reports cannot be overemphasized. An incident or occurrence that has caused (resulted in) harm and that may possibly (has the potential to) expose the facility to professional or custodial liability claims is termed a potentially compensable event (PCE).

The QUALITY ASSURANCE GUIDE states that written guidelines must be incorporated in local command instructions that will answer the questions: who, when, where, and how with regard to incident reporting. The staff must be provided with clear written explanations describing?

(1) The importance of incident reports.

(2) The proper completion of incident reports.

The instruction states that active physician involvement in the risk management program is essential if the system is to be effective. Even though individual Navy health care providers are not subject to suit, the Federal Government is liable for the negligent acts of its employees, physicians, nurses, and other allied health personnel. For this reason,

it is essential that physicians report medically-related injuries to patients.

The QUALITY ASSURANCE GUIDE stresses that the incident reporting system is not to be viewed as a punitive system, and that the information shall not be used for censuring the parties involved in the incident. Rather, the reports are an administrative mechanism designed to alert the risk management teams when an event occurs that may negatively affect the hospital's liability exposure or patient satisfaction. [Ref. 84]

The QUALITY ASSURANCE GUIDE recommends utilization of high risk generic screening criteria which should serve as a warning flag that an adverse event has occurred. This list of criteria should not be adopted without consideration of the facility's individual needs. The following are examples of occurrences when an incident report should be required:

(1) All procedural errors.

(2) All falls (with or without injury).

(3) All equipment failures during procedural use (with or without injuries).

(4) All medication errors (by physician, nursing service personnel, or pharmacy personnel).

(5) All serious expressions of patient dissatisfaction. [Ref. 85]

In addition, the instruction requires that each service, department, or committee establish an incident reporting or monitoring system as part of its quality assurance activities.

Use of the Medical Facility Incident Report (NAVMED 6300/11) is required for incident reporting. The QUALITY ASSURANCE GUIDE STATES that guidelines must be provided on how it will be completed, processed, and filed. Additionally, it is stressed that this report not become a part of the patient's medical record. No notation is to be entered in the medical record regarding the filing of an incident report. The instruction cautions against the use of the words error, mistake, incident, or accident in the patient's record. Furthermore, the instruction stresses that confidentiality must be maintained at all times and that reports are to be securely filed. [Ref. 86]

The completed report is required to be routed via immediate department heads of involved individual(s) to the responsible directorates. This routing should occur within 24-48 hours and the risk coordinator is expected to be involved in giving assistance and in hastening the completion of this phase of the process. The instruction suggests specific actions that the risk coordinator is expected to take in order to expedite this process, as directed by the executive officer.

A summary analysis of incident reports with findings is required to be completed semi-annually and forwarded to the appropriate geographic naval medical command. Each geographic region commander is responsible for developing the standardized format for this report that best suits its

resources. The compiled incident data developed is expected to provide information about categories which can be used in developing trends and patterns for a comparative analysis.

The instruction recognizes that several treatment facilities have computerized their incident reporting systems. Geographic naval medical commanders may give written permission for treatment facilities to use alternative methods of reporting incidents (i.e., computerized forms) if the data elements of NAVMED 6300/11 are collected by the treatment facility, and the geographic naval medical command can use the data to perform a comparative analysis with other treatment facilities. [Ref. 87]

b. Chapter 2. Utilization Review Functions

Chapter two of Section F, the final chapter of the QUALITY ASSURANCE GUIDE, sets forth the requirements and guidelines for all MTF's and DTF's to establish a utilization review (UR) program as an integral part of their command-wide QA program. The instruction defines utilization review as a method for assessing the quality of patient care based on a measured comparison of the use of health care resources with predetermined criteria on the need for care. Utilization review may be done concurrently; at the time the patient is receiving care, or retrospectively; after the patient has received treatment.

Public law mandates that facilities review cost and quality of patient care delivered under any Federal

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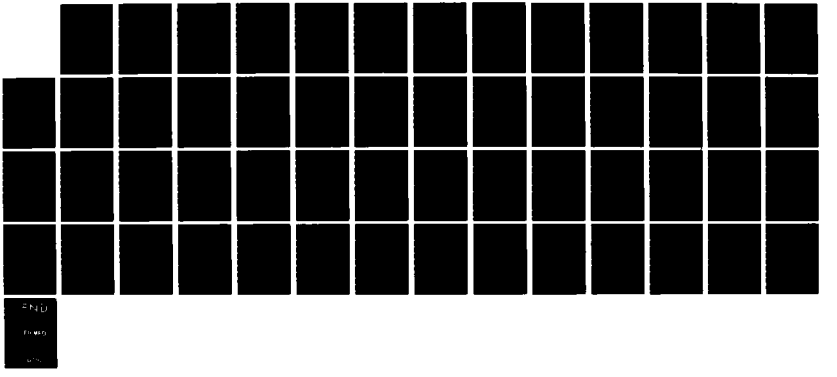

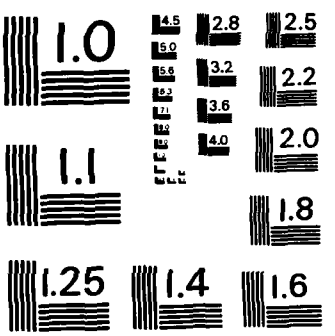

program. The three main components of this required review are: (1) Concurrent review, (2) medical care evaluation studies, and (3) profile analysis. The standards of the JCAH were specifically referred to in Public Law 89-97 (Medicare) enacted in 1965, reflecting the confidence of the Congress in the ability of the JCAH to provide optional norms and to assess the quality of care provided. With regards to utilization review, legislative requirements and the requirements of JCAH are basically the same.

Despite government regulations, health care costs have continued to escalate. Existing methods and approaches have not achieved satisfactory results in terms of cost. The instruction states that in all MTF's and DTF's, utilization review is not to be considered merely a routine carried out in the interest of meeting JCAH requirements, but rather:

(1) An instrument to be used in providing the best possible cost effective care for patient populations.

(2) A medium for education of the medical staff and other health professionals.

(3) A basis for comparative studies within and among naval MTF's and DTF's.

(4) A foundation for making necessary changes. [Ref. 88]

Accordingly, the instruction views the utilization review process as an essential component of the facility-wide QA program, and its monitoring effectiveness is expected to be dependent upon open lines of communication with all other QA monitored activities.

Each hospital is required to write and implement an UR plan. The instruction states that the UR function must be reviewed and evaluated at least annually, including a review of the written plan and the written criteria, including length of stay norms.

The QUALITY ASSURANCE GUIDE provides the following objectives for the utilization review program:

(1) To deal quickly with problems involving deficiencies in care, such as improperly ordered tests, untimely tests, or incidents that disrupt normal patterns of care and increase costs.

(2) To insure beds are properly utilized and that admission priorities are followed.

(3) To reduce as much as possible the chance of liability for both physician and facility.

(4) To maintain the highest possible standards of nursing care and support services.

(5) To use the program as an educational process for staff and physicians alike.

(6) To assure the patient receives neither more care (overutilization) nor less care (underutilization) than he/she needs; thereby assuring that care is: (1) medically necessary; (2) delivered in the most economical way; and (3) in conformity with accreditation standards and to criteria established by physician peer review process.

Additionally, it is required that utilization review criteria be written for two essential reasons: standards to measure quality of service provided, and in defense of complaints to prove that quality services are being provided. Criteria are to be written for at least the timeliness of service or target turnaround times. [Ref. 89]

The QUALITY ASSURANCE GUIDE requires that the commanding officer make the following appointments for the utilization review program:

(1) Physician Reviewers

(2) Utilization Review Coordinator

(3) Utilization Review Committee

The instruction provides three alternative methods for concurrent utilization review, and each command is required to select the method that best fits its resources and the size of the facility. The three methods are as follows:

(1) Method one. Admission review (AR) plus continued stay review (CSR) utilizing pre-established criteria and length of stay norms provided by a professional activity study (PAS).

(2) Method two. Intensity of Service, Severity of Illness and Discharge (ISD) screening criteria used with the Interqual's Cyclic Review System.

(3) Method three. Appropriateness evaluation protocol (AEP) Method. [Ref. 90]

The QUALITY ASSURANCE GUIDE requires the UR coordinator to submit to the commanding officer via the chain of command a monthly summary report to provide a basis for evaluation of patterns of care and for the initiation of corrective action as necessary.

III. COMPARATIVE ANALYSIS OF JCAH QUALITY ASSURANCE REQUIREMENTS AND THE NAVAL MEDICAL COMMAND QUALITY ASSURANCE PROGRAM INSTRUCTION

A. METHODOLOGY OF COMPARATIVE ANALYSIS

During the course of the comparative analysis, the authors found that information and recommendations for implementation of a quality assurance program provided by the JCAH were not completely compatible with the organizational structure which exists at a MTF. Accordingly, the structure of the NAVMEDCOM QUALITY ASSURANCE GUIDE does not directly reflect that of the QA structure recommended in the JCAH Quality Assurance publications discussed in Section B of Chapter two.

Given this limitation, the authors chose to compare the requirements established for an acceptable quality assurance program by the various JCAH publications with those established by NAVMEDCOM in the QUALITY ASSURANCE GUIDE, by means of a chapter by chapter review of the instruction. Since the JCAH failed to provide an example of a clearly developed QA program which could serve as a model for comparison, the authors were forced to interpret what they felt were the JCAH objectives of a quality assurance program with respect to each of the functional areas.

Additionally, the authors chose to assess the extent to which the QUALITY ASSURANCE GUIDE emphasized the NAVMEDCOM goal that each MTF ensure its patients receive the best

possible health care allowed by its resources. Included in this assessment were issues such as clarity of objectives, ease of implementation, required MTF staff involvement, and the interrelationship of quality assurance components.

Although the QUALITY ASSURANCE GUIDE was written utilizing JCAH guidelines for quality assurance, the JCAH disclaims any responsibility resulting from direct implementation of their recommendations during establishment of medical quality assurance programs. Given the JCAH disclaimer, the resulting lack of specific examples and recommendations in its publications, and the unique command structure found at MTF's (as compared to that of a civilian hospital), NAVMEDCOM was forced to interpret such JCAH guidelines for use within the framework of a military treatment facility. [Ref. 91]

B. NAVMEDCOM QUALITY ASSURANCE GUIDE DEVIATIONS FROM JCAH QUALITY ASSURANCE REQUIREMENTS/CRITIQUE OF INSTRUCTION

1. Section A--Principles and Methods for Establishing a QA Program

In describing the elements of a written QA plan, the QUALITY ASSURANCE GUIDE states that the commanding officer bears ultimate responsibility for the quality assurance program, and that the plan should include mechanisms for the delegation of responsibility and accountability for the command-wide QA program. [Ref. 92]

This implies to a reader that the commanding officer may delegate his responsibility, which in fact, appears to be a contradiction, as one cannot delegate responsibility;

only authority and accountability. Commanding officers remain responsible for the QA program regardless of their actual involvement. Furthermore, since the instruction states that the executive officer shall be appointed as overall manager of the command QA program, the inference to the reader is that the executive officer is responsible, de facto, for the QA program. The authors believe this is not the intent of the instruction.

In describing the requirements for the position of quality assurance coordinator, the QUALITY ASSURANCE GUIDE states that the person filling this billet should attend basic out-service QA workshops during the first six months in the assignment. [Ref. 93] Additionally, the JCAH QA GUIDE suggests that in an assessment analysis of a facility's QA program, individuals should have appropriate knowledge and skills to perform the duties of a specific QA function.

In view of the fact that the quality assurance coordinator is a "key player" in the command QA program, it is the author's opinion that this individual should be required to receive appropriate QA training prior to assuming such responsibilities. Just as a prospective aviation safety officer is required to attend Aviation Safety School prior to assuming his duties in a squadron, so too should the quality assurance coordinator be required to receive appropriate training prior to assuming his duties in an MTF.

Additionally, the Navy QUALITY ASSURANCE GUIDE allows for a lack of continuity in the quality assurance coordinator

position. The instruction makes no mention of the need for continuity in the QA coordinator position, and as a result, allows for frequent personnel turnover in this critical position at a MTF. Since the instruction suggests that the QA coordinator not be a new staff member (and given the frequent permanent change of station rotation of hospital staff), the authors recommend a specific billet designator be required for an individual assuming the QA coordinator position.

Although the QUALITY ASSURANCE GUIDE requires that the QA coordinator maintain an up-to-date collection of references pertinent to quality assurance, no specific guidelines are set forth with respect to what types of materials should be maintained. The JCAH QA GUIDE provides a list of selected references on quality assurance which the authors feel should be maintained and updated, at a minimum, as part of a MTF QA library.

The QUALITY ASSURANCE GUIDE does not currently require the physician head/QA advisor to have formal QA training prior to assuming this position. While the instruction requires that the physician head/QA advisor attend the JCAH Medical Staff Issues workshop, it does not state that this must occur prior to assuming the position, which the authors feel should be the case.

Furthermore, and as was the case with the QA coordinator position, the instruction fails to address the issue of continuity in the position of physician head/QA advisor.

As this too is a critical billet within a command QA program, the authors believe that the instruction should place an emphasis on continuity, and that every attempt be made to minimize rotation within this billet.

In addressing the selection of an appropriate sample for problem assessment, the QUALITY ASSURANCE GUIDE suggests procedures for statistical sampling which may in fact not be valid in all situations. The sampli..g techniques suggested by the instruction rely heavily upon the central limit theorem [Ref. 94], which is not applicable to all statistical samples. Rather than possibly confusing the reader (who may not have a strong background in statistical sampling procedurs), the authors feel that a better approach might simply be for the instruction to provide a list of references which the reader could utilize on an as-needed basis while performing such tests.

2. Section B--Medical Staff QA Functions and Activities

The information provided in this section is in the authors' opinion, evasive, obscure, and condescending with regard to required medical staff involvement in the QA program. While the objectives of this section are clearly stated, the semantics of the instruction fail to stress the critical importance of medical staff involvement. Given that physicians were responsible for 84% of medical liability claims paid by the Navy in 1983 alone [Ref. 95], the authors feel that a much stronger emphasis should be placed on medical staff functions and activities.

Although the QUALITY ASSURANCE GUIDE recognizes that physicians have been reluctant to confront their peers, the instruction avoids directly confronting the issue of peer review in the objectives provided for medical staff QA monitoring requirements. The JCAH states that individual medical staff members are to be held accountable for the quality and appropriateness of care rendered to their patients. Furthermore, the JCAH requires that peer reviews demonstrate medical staff accountability to the governing body of the facility while helping to identify needs for change in behavior, education, changes in privileges, policy decisions, and systems and procedures provisions. JCAH states that the overall goal of peer review is the establishment of a uniform level of quality care within the institution. [Ref. 96] The QUALITY ASSURANCE GUIDE does not clearly elucidate these aforementioned JCAH medical staff QA objectives.

In defining the principles, policies, and organization of the medical staff, the instruction states that there "should" be required attendance at quality assurance education programs to ensure that the medical staff possesses a working knowledge of the principles and process for conducting QA activities. The QUALITY ASSURANCE GUIDE glossary of terms defines "should" as: "a term used to reflect the commonly accepted method, yet allowing the use of commonly accepted alternates." The authors feel that the imperative "shall" would have been the appropriate term to use in this case

since the QUALITY ASSURANCE GUIDE glossary of terms defines "shall" as: "a term used to indicate a mandatory statement; indicates the only acceptable method." In view of the critical importance of medical staff involvement in the quality assurance program, ongoing education in this area seems a valid and essential requirement.

In recognition of the QA coordinator's liaison position with the medical staff, the QUALITY ASSURANCE GUIDE states that there "should" be acceptance and compliance by the medical staff with his or her directions and suggestions. Since the QA coordinator position is clearly considered significant by the instruction, and once again given the use of the word "should," the instruction seems to imply that acceptance of suggestions provided by this person may be optional. The authors feel this wording is unacceptable as it may encourage medical staff disregard for potentially significant quality assurance suggestions.

The chapter describing monthly clinical service or department meetings fails to describe, at the outset, the objectives for such medical staff meetings. While this chapter describes the process of peer review without specifically naming it as such, it fails to state that peer review is the primary function of these meetings, as suggested by JCAH. [Ref. 97] It is the authors' observation that throughout Section B, use of the words "peer review" have been studiously avoided.

The medical record review chapter in Section B places significant emphasis upon compliance with JCAH accreditation requirements. While this emphasis is obviously necessary to ensure compliance with JCAH requirements, it may result in "a check in the block" attitude on the part of the medical staff, thereby failing to provide proper emphasis on the real need: quality medical records.

JCAH BACK TO BASICS suggests the provision for concurrent review of medical records. NAVMEDCOM failed to include the requirement for such in the instruction. During concurrent medical records review, charts are randomly selected from each nursing station and checked weekly to determine the adequacy of the medical record while the patient is still in the hospital. This methodology has considerably improved the timely completion of histories and physicals, progress notes, and other factors of concurrent patient care. [Ref. 98]

Since the medical record is such a critical link in the chain of medical care, the authors feel the QUALITY ASSURANCE GUIDE should place more emphasis on such matters as legibility, completeness, and medico-legal appropriateness of entries in the record keeping as:

> keep the record in such a fashion that if all practitioners treating a patient were suddenly to disappear, a new team coming on the scene could, from the record alone, immediately continue the best possible treatment. [Ref. 99]

Given the aforementioned criterion, the instruction appears lacking in providing specific guidelines to avoid potential difficulties in this area.

3. Section C--Support Services (Ancillary Departments) QA Functions and Activities

No deviations from JCAH standards were noted during the review of this section. However, the authors feel that the guidelines provided in the QUALITY ASSURANCE GUIDE are inadequate for the development of a support service unit QA plan. Since MTF's may lack personnel with sufficient experience and training necessary for the initial establishment of a quality assurance program for their particular support services, the instruction should have more specific examples.

4. Section D--Free-Standing Ambulatory Care QA Program

No deviations from JCAH guidelines were noted during the review of this section. Comments regarding the possible lack of experienced or trained personnel at MTF's from Section B apply equally to this Section.

5. Section E--QA Program for Free-Standing Dental Clinics

Since there are no JCAH accreditation requirements for free-standing dental clinics, there were obviously no deviations found from such in this section. However, the QA program for free-standing dental clinics section is the most specific of all the sections in the QUALITY ASSURANCE GUIDE with regard to the directives provided for the establishment of a quality assurance program. The elements are concisely stated and would enable a relatively inexperienced individual to establish an operative quality assurance program with a minimum amount of confusion. Additionally, the problem identification chapter provides excellent examples

which could be utilized to evaluate all the parameters of dental care previously identified in chapter two of this section.

6. Section F--Integration of Risk Management and Utilization Review into the QA Program

Although the QUALITY ASSURANCE GUIDE combines the concepts of quality assurance and risk management, a distinction must be made between the two. The latter may be defined as control of those circumstances of hospital health care which pose a threat to the safety and comfort of patients. In a word, it means elimination of mishaps. Risk management is part of quality assurance, but alone it neglects the deficiencies that make the difference between adequate, even good, care and excellent care. [Ref. 100]

The three JCAH Quality Assurance publications which the authors reviewed in chapter two of this thesis contain no information regarding risk management. However, the JCAH ACCREDITATION MANUAL FOR HOSPITALS, 1985, specifically addresses the requirement for both, utilization review and review of accidents, injuries, and safety hazards in its standards for accreditation of a quality assurance program. [Ref. 101] To this end, NAVMEDCOM has combined quality assurance, utilization review, and risk management into one instruction.

The JCAH standards for review of accidents, injuries, and safety hazards in the JCAH ACCREDITATION MANUAL FOR HOSPITALS, relate exclusively to potential problems with

custodial liability. The QUALITY ASSURANCE GUIDE addresses both custodial liability and deficiencies in medical care. To this extent, NAVMEDCOM has recognized the need to involve the risk of professional negligence in the risk management program, and has specifically addressed such in the QUALITY ASSURANCE GUIDE.

This risk management section of the instruction clearly addresses the objective of providing the highest quality of patient care possible. In preceeding sections of the QUALITY ASSURANCE GUIDE, the review and evaluation functions were stressed without clearly stating that the overall purpose of such is to provide the highest quality of patient care possible. It is the authors' opinion that the section on risk management provides excellent guidance, and if adhered to, would allow a command to reduce potential risk.

The QUALITY ASSURANCE GUIDE section regarding utilization review provides sufficiently extensive guidance for the establishment of a utilization review program. There are no apparent deviations from the JCAH standards for accreditation of utilization review. However, the background discussion provided in this section requires updating, as the law regarding Professional Standard Review Organizations (PSRO) has been changed recently, which has altered the PSRO mission.

C. GENERAL RECOMMENDATIONS FOR CORRECTIVE ACTION ON THE QUALITY ASSURANCE GUIDE

The authors feel that the QUALITY ASSURANCE GUIDE meets the basic JCAH accreditation requirements for an acceptable

QA program. However, several of the sections in the instruction should provide more extensive guidance for the actual implementation of a command quality assurance program. While it is realized that the size and complexity of MTF's vary significantly, and that the QA program established at each facility will be dictated by the aforementioned factors, it is nevertheless incumbent upon NAVMEDCOM to provide at least rudimentary criteria and working models of successful programs. Since the JCAH refuses to assume responsibility for its quality assurance program recommendations, the authors feel it should be the responsibility of NAVMEDCOM to provide more specific information and examples.

The QUALITY ASSURANCE GUIDE section on medical staff QA functions and activities appears too evasive to be truly effective. Since the instruction states that,

> Because the overall responsibility for the quality of medical practice rests with the medical staff, the individual staff member must be held accountable for the quality and appropriateness of care rendered to their patients. [Ref. 102]

And furthermore,

> The medical staff is an essential force for maintaining quality assurance. [Ref. 103]

It is the authors' recommendation that the instruction be revised to more specifically direct the actions of medical staff. Recommended improvements include the requirement for implementation of a medical records concurrent reivew process, that the peer review process be specifically identified as such, that minimum medical staff quality assurance education

requirements be established, and that more emphasis be placed on medical staff acceptance of the QA coordinator's suggestions and recommendations.

In order to achieve greater medical staff acceptance of the QA coordinator's suggestions and recommendations, it is recommended that the physician head/QA advisor and the QA coordinator come to prior agreement on issues before presentation of recommended QA actions at medical staff meetings. Furthermore, it is felt that implementation of these recommendations should be mandatory unless the medical staff has overriding objections which can be documented.

It is the authors' impression that throughout the QUALITY ASSURANCE GUIDE, with the exception of the section on risk management/utilization review, more emphasis is placed on simply meeting the JCAH accreditation requirements for a QA program than on the objective of providing quality care. Although the QUALITY ASSURANCE GUIDE states,

> The mission of each naval MTF/DTF is to ensure that its patients receive the best possible health care its resources can provide, [Ref. 104]

the primary concern throughout the instruction appears to have been to provide a vehicle for the somewhat mechanical establishment of a QA program which would meet JCAH accreditation standards.

Stanley A. Skillicorn, M.D., a renowned authority on medical quality assurance, states that a quality assurance program is predicated on a very different approach to that

which the authors suggest that NAVMEDCOM took while writing the QUALITY ASSURANCE GUIDE.

> . . . quality happens when everyone does everything exactly right every time. Quality of patient care is perfection of patient care. If the definition appears vague and unrealistic, the effect of the approach has been just the contrary. We have begun to turn around the mentality that is satisfied with just meeting minimum standards. Fulfilling licensure, Joint Commission, continuing education, and other requirements are no longer goals but processes. Incident reports are no longer used just to identify possible liability cases and blatant incompetence, but also as means of discovering trends and underlying deficiencies. Medical audits--studies made to evaluate patient care--are no longer performed merely as a duty to be completed as fast as possible, but as revealing investigations; indeed, some members of the medical staff have begun to ask for audits. And a number of audits have even been performed on administrative matters. [Ref. 105]

To this extent, the authors feel that while NAVMEDCOM has provided an acceptable means for meeting JCAH accreditation standards and the reduction of potentially compensible events, it has failed to stress the real goal of quality assurance.

IV. NAVY MEDICAL MALPRACTICE LITIGATION REVIEW

A. METHODOLOGY OF MALPRACTICE LITIGATION REVIEW

The authors' malpractice litigation review was conducted during the week of 16 June, 1985, by examining Navy medical malpractice claims files for which the final disposition determination was made during fiscal year 1984. This data was obtained through the cooperation of the Navy Inspector General's office. Completed malpractice claims files are held on file at the Navy Judge Advocate General Headquarters, located in the Hoffman Building in Arlington, Virginia and were examined on site by one of the authors.

The purpose of the medical malpractice litigation review was to determine if a set of "key variables" could be developed as a means for assessing the adequacy of an existing MTF quality assurance program. The objective of identifying this set of "key variables" is to provide a tool which will enable a manager or an auditor to determine the favorable or unfavorable performance of an existing QA program. For example, the peer review "key variable" would be utilized to assess if peer reviews were in fact being conducted at a facility, and if so, whether the results were being documented. Furthermore, these "key variables" might allow a manager or an auditor a less costly and less time consuming alternative to indepth assessments.

Since the number and length of completed malpractice claims far exceeded the time available for a complete review and analysis of all such claims for the fiscal year 1984, the authors chose a random sample of the claims available. Several of the completed malpractice claims files were subsequently rejected by the authors for some or all of the following reasons:

(1) Files were incomplete because the Navy Judge Advocate disallowed the claim due to the Feres Doctrine. Under the Feres Doctrine, a Supreme Court ruling, active duty personnel cannot sue the government for injuries incident to or arising out of their military service. The investigation was terminated and the claim denied on that basis.

(2) The statute of limitations had expired for filing a claim. As a result, no further investigative action was taken by the Judge Advocate General.

(3) Even though the claim was filed in the medical malpractice section of the Judge Advocate General, the actual reason for the claim was determined to be the result of an accident or injury which was clearly unrelated to the medical treatment received after that accident or injury.

(4) Claims filed were never settled because the plaintiff failed to pursue litigation, and the file was subsequently closed after a specified period of time.

As a result, only twenty completed malpractice claims files contained the detail necessary to complete the authors' review. The claims evaluation process was conducted using a formatted guide (see Appendix A) prepared by the authors on which specific questions were addressed for each claim reviewed. This formatted guide proved useful in attempting to categorize and develop "key variables."

With the information provided in each case, the authors attempted to categorize the cause of the litigation into one or more of the following three areas:

(1) Knowledge. A case which resulted from apparent lack of professional knowledge on the part of physician staff, nursing staff, support/ancillary service staff, or other staff members at a MTF.

(2) Negligence. A case which resulted from either an overt or covert act of negligence on the part of a staff member, or resulted from a staff member performing a procedure which the individual knew he was clearly not qualified to perform.

(3) Failures. A case which resulted from the failure of equipment, physical attributes of the facility, or a failure of any organizational system within the MTF, or any combination of the failures listed above.

In addition to the above categories, the authors further attempted to determine, on a subjective basis, whether the cases were the result of preventable or nonpreventable causes.

While the preceeding guide proved useful during the review, it was not entirely satisfactory for categorizing the broadly defined causes found in each case. In retrospect, a more satisfactory and all-encompassing set of categories would have been delineated as: Lack of professional knowledge, lack of adequate organizational systems, and inadequate facilities or equipment.

B. REVIEW OF COMPLETED MEDICAL MALPRACTICE CLAIMS

Of the twenty cases examined in detail, the authors classified nine as resulting from lack of professional knowledge, nine as resulting from negligence, and sixteen as

resulting from failures. The total classification exceeds the twenty cases reviewed because several of the cases resulted from causes classified into more than one of the three broad categories mentioned above.

Cases categorized by the authors as arising from lack of professional knowledge resulted from occurrences such as lack of staff knowledge regarding preoperative patient counselling requirements; physicians lacking adequate knowledge and training required for a particular operative procedure performed; physicians and other staff members failing to possess knowledge necessary to recognize symptoms of impending emergencies and to perform requisite actions; and physicians and other staff members failing to know and recognize the need for follow-up procedures.

Malpractice litigation cases which the authors classified as resulting from negligence were found to involve incidents such as: improper supervision and procedural training of resident physicain trainees; release of potentially dangerous substances under questionable circumstances; failure of patient contact points (such as patient appointment centers, emergency vehicle dispatch, and nursing stations) to recognize potentially critical situations and take appropriate action; physicians knowingly performing procedures for which they had not been granted privileges; careless surgical procedures; failure to properly document medical records; and failure to ensure proper patient follow-up.

The greatest number of malpractice cases reviewed were classified by the authors as belonging within the failures category. The spectrum of associated causes here ranged from deficiencies in medical treatment protocols to purely administrative shortcomings in the organizational system.

Cases of malpractice litigation which were categorized as failures during the authors' review included: failure to properly assess personnel training prior to assignment of such persons to critical patient care positions; failure to establish proper patient transfer procedures between treatment facilities; failure to establish adequate safeguards for dangerous substances; failure of the facility QA program to detect, in a timely manner, repeated cases of individual physician substandard professional performance, and failure of the commanding officer to remove such individuals' privileges; failure to establish adequate patient preoperative consent procedures; failure to establish standard medical treatment protocols for management of commonly encountered medical situations; failure to establish adequate means to ensure that patient follow-up occurs when required; failure to establish a means by which critical patient care information is passed to the attending physician in a timely manner; failure to ensure adequate life support equipment is available before a procedure is initiated which may require such; and, failure to establish a system whereby medical records are properly and legibly documented, include

all forms required for the specific patient's record, and are properly filed and stored for retrieval when needed.

C. DEVELOPMENT OF QUALITY ASSURANCE PROGRAM "KEY VARIABLES"

As evidenced by the preceeding malpractice litigation review, the causes attributable to medical malpractice litigation within the Navy are extremely diverse. This diversity is indicative of the complexity required of a quality assurance program which is meant to reduce the incidence of such problems. Accordingly, the "key variables" developed to produce information regarding potential problems within a QA program must be equally encompassing.

In describing the design of a management control system and the development of "key variables," Robert Anthony states:

> A management control system should be designed to facilitate planning for the implementation of strategies, to motivate managers to achieve organizational goals, and to develop information for the evaluation of performance in achieving goals. It relies heavily on measurements to do this; and to measure effectively, the strategy must lend itself to measurement of performance, and the management control system must be designed to provide suitable measures. If either does not exist, the management control system can be of little help in implementing the strategies. [Ref. 106]

The management control system may help implement strategies by ensuring development of measures of the performance of certain key activities of the organization that normally lead or indicate the future success of the organization. These variables are called "key variables." In most situations

there will be "key variables" for the organization as a whole and other, perhaps different, "key variables" for division or other segments within the organization. [Ref. 107]

The development of means of identifying and measuring "key variables" to implement strategies represented signal improvement in the technology of management control systems. The identification of "key variables" requires a thorough understanding of the operation of the organization. [Ref. 108] Some help in identifying "key variables" can be found by developing a model of the QA program and examining such to discover sensitivities to the quality of care rendered. According to Anthony [Ref. 109], indications provided by a "key variable" seem to have the following characteristics:

(1) It is important in explaining the success or failure of the organization.

(2) It is volatile and can change quickly, often for reasons not controllable by the manager. For example, the commanding officer of a facility has no direct control over each case treated. However, through the process of peer review, he can retospectively assess the appropriateness of care rendered, and take corrective action as may be deemed necessary.

(3) It is significant enough that prompt action is required when a change occurs. For example, when a physician has performed incompetently, immediate action would be indicated. A peer review "key variable" would provide indications of such incompetence to the appropriate persons in charge to allow for immediate corrective action.

(4) It is not easy to predict changes in the key variable. For example, a surgeon may have performed exceptionally well in the past, yet as a result of recent personal problems, the surgical procedures performed by this individual suddenly indicate several instances of lack of judgment. A peer review "key variable" would be intended to detect such instances.

(5) The variable can be measured, either directly or via a surrogate. For example, patients' satisfaction cannot be measured directly, but its surrogate, the number of patient complaints elicited by the patient satisfaction surveys, can be a key variable.

The five general characteristics of a "key variable" described above served as guidelines for development of the authors' "key variables" for the quality assurance program.

In addition to the medical malpractice case review, the authors solicited information for the development of "key variables" from interviews conducted with personnel located at NAVMEDCOM, two GEONAVMEDCOMS, a major naval hospital, and from numerous discussions with the Navy Inspector General. Since NAVMEDCOM has stated the goal of each MTF is to ensure that its patients receive the best possible health care its resources can provide, and since the quality of military health care has recently received widespread attention, the authors have attempted to develop a means by which to measure the effectiveness of quality assurance programs.

1. Physician Qualifications

The first "key variable" proposed for the QA program is physician qualifications. The development of this "key variable" relates to the category "knowledge" described during the malpractice litigation review process. Since the physician is the primary provider of medical care within a facility, and physicians are responsible for the vast majority of medical malpractice settlements within the Navy, the proper identification and validation of professional qualifications seems essential.

Complete documentation of the credentials review process indicating adherence to the requirements of NAVMED-COMINST 6320.8, Credentialing Program (Credentials Review Process), dated 12 September 1984, should be available and on file for all physicians practicing medicine at a particular facility. This file should include both pertinent and verified information regarding the credentials submitted by the prospective applicant during the recruitment and hiring process. Additionally, it should be required that this file contain information from all facilities the physician has practiced medicine in the past, and include letters of reference from the incoming physician's department chairman and commanding officer at each of these facilities. This file should also contain specific evidence indicating that the credentials were reviewed by the executive committee of the medical staff upon a physician's arrival at the facility, and prior to the granting of clinical privileges, as is required by the QUALITY ASSURANCE GUIDE.

In addition to evidence indicating that the credentials have been reviewed and verified, the physician qualifications "key variable" requires that documentation pertaining to the granting of clinical privileges be maintained by the facility. As a primary consideration, the granting of clinical privileges to physicians should clearly not exceed the documented qualifications which were verified during the credentials review process. The clinical privileges file

maintained by the facility on each physician should contain documentation of the entire process, from the physician's initial request for privileges, to the final granting of such by the commanding officer. Furthermore, this file must contain evidence revealing that privileges, once granted, are periodically reviewed. This periodic review should consist of both, the applicability of the privileges granted with regard to the medical care area the physician is assigned, and that the physician is deserving of privileges granted based upon past and current performance in this area.

As evidenced by the authors malpractice litigation review and recent cases which have received extensive media coverage, credentialing and privileges have been a major source of problems within the Navy medical community. Malpractice cases reviewed by the authors have indicated that privileges are sometimes exceeded, or are not removed when actions would indicate otherwise. In order for the physician qualifications "key variable" to be useful, it is incumbent upon management to insure that credentials are reviewed, and privileges monitored and documented with the utmost care. Moreover, there should be no case where a physician's privileges have not been reviewed, as required, within the time limits specified by NAVMEDCOMINST 6320.8. Incidents involving unsatisfactory performance, or cases where the physician clearly exceeded his privileges granted, must be documented for use during the future assessment of

privileges granted. The "key variable" physician qualifications requires all the aforementioned documented evidence be present in oder to there to be positive indications of a QA program.

2. Peer Review

The peer review "key variable" is meant to provide information regarding whether a regular review and evaluation of the quality and appropriateness of patient care provided by each physician is occurring. This "key variable" relates to all three of the categories described by the authors in the malpractice litigation review.

For example, a peer review system should detect cases where a particular physician clearly failed to demonstrate the knowledge or skill required for an operative procedure performed. Peer review should also detect cases where a physician exhibits negligence such as having attempted a procedure for which he knew he was not qualified. Finally, the peer review system should detect physician-related treatment failures which have occurred on a repeated basis, provided the system produces the statistical evidence for such.

Documented information provided for the peer review "key variable" must indicate peer reviews are occurring on a regular basis, and that problem detection is in fact aggressively pursued. However, this alone is not sufficient for indications of an adequate QA program. This process must also show evidence of a mechanism whereby peer reviews

are triggered by incident reports which reveal physician related problems with patient care. Regardless of the source, documentation must be present indicating positive action was taken to correct problems revealed during all aspects of the peer review process, and reflect that adequate follow-up has in fact occurred.

3. Medical Staff Statistical Reviews

The authors suggest a "key variable" titled medical staff statistical reviews in order to provide information on problem areas which exist within the required medical staff review functions of the quality assurance program. This key variable requires that documentation be made available supporting a statistical review of the following medical staff review functions which are required by the QUALITY ASSURANCE GUIDE:

(1) Mortality and morbidity review

(2) Pharmacy and therapeutics review

(3) Blood utilization review

(4) Surgical case review

(5) Antibiotic clinical usage review.

This statistical information should provide for the ongoing assessment by the medical staff of the key areas listed above. Review of such information should allow detection of areas which statistically deviate from standares previously established by the medical staff.

Problem areas revealed by these statistics must be documented, and clearly indicate the corrective action and

follow-up taken. For example, if surgical case review indicates a statistically high incidence of post-operative infections originating from procedures performed by a certain department, documented evidence should exist illustrating that the department head took both the action required to correct the problem and implemented procedures to avoid such occurrences in the future.

4. Medical Records

The medical records "key variable" directly relates to the failures category mentioned in the authors' medical malpractice review. Medical care provided by a facility may be superb, yet if this care is not completely documented, or if the documentation is so illegible that it is of no use to other practitioners, the result may lead to a failure of the system such that the patient receives grossly inappropriate care.

Concurrent and retrospective medical record reviews should address not only the quality and appropriateness of care rendered, but the timeliness, completeness, correctness, and legibility of entries as well. The authors realize that the ideal goal for a MTF is medical records which are 100 percent problem-free. However, the authors also realize that this goal is realistically unattainable. Nevertheless, there should be evidence indicating that efforts have been made to reduce the percentage of errors noted, and to increase the timeliness of entries. Furthermore, there must be

evidence indicating that not only is all pertinent information included in medical records, but that entires are 100 percent legible. It is incumbent upon the medical staff to not only establish both quantifiable and attainable goals for the medical record review process, but they must also strive to attain these goals 100 percent of the time.

The medical record "key variable" should be supported by documented information indicating whether concurrent and retrospective medical record reviews are in fact being conducted, and whether these reviews result in aggressive action on the part of the facility to correct deficiencies noted during this review process.

5. Panic Devices

The panic devices "key variable" is associated with a facility's need for a mechanism to be present which deals efficiently and effectively with potential life threatening situations. The need for this "key variable" relates directly to the failures category described in the authors' malpractice litigation review.

For example, procedures should exist which facilitate corrective action: if the laboratory service discovers an adverse laboratory finding; if radiology uncovers a previously undiscovered, yet potentially debilitating fracture; if the pharmacy uncovers a patient-related contra-indication after a prescribed medication has been dispatched. And, if in each of these cases the primary care provider is unaware that

such a situation exists, then a mechanism must be in place whereby the urgency of the situation is immediately communicated to the primary care provider.

There must be evidence that the organizational system at a MTF has such a clearly defined and documented "panic device" by which each department communicates such urgencies, and that a feedback mechanism exists to ensure that the appropriate persons in fact have received the critical information. In order for this "panic device" to be effective, there must be indications that the actions required in fact occur in every case when adverse patient findings are discovered. The panic devices "key variable" not only requires information regarding the presence of such a device, but that furthermore, there be evidence of proper implementation.

6. Risk Management

The need for the risk management "key variable" is associated with all three of the categories described by the authors during the malpractice litigation review. While the authors realize that an integrated risk management system is already required by the QUALITY ASSURANCE GUIDE, it is our intent that a "key variable" be provided for assessing the effectiveness of the aforementioned system.

The ultimate goal of the risk management program is to prevent (dollar) loss [Ref. 110]. It is therefore incumbent upon the MTF to continually assess its susceptibility for loss, and to take corrective actions which may be necessary

in order to reduce the risk of such loss. Information for this "key variable" should include the following sources:

(1) Incident reports

(2) Morbidity and mortality committee minutes

(3) Department minutes

(4) Quality assurance committee minutes

(5) Inspector general reports (both Navy IG and NAVMEDCOM IG)

(6) Patient complaints

(7) Congressional inquiries

(8) JCAH reports

(9) Patient satisfaction surveys. [Ref. 111]

Problems revealed from the preceeding sources of information should be used as indications of the overall risk reduction efforts which have occurred at a facility. Each of these sources may suggest different types of problems, however, the paramount issue this "key variable" is meant to address is how effectively the facility utilizes such information, and whether it takes subsequent risk reduction action.

The risk management "key variable" also requires that a mechanism exist for the communication of risk-related problems within a facility, and that evidence be present indicating that a coordinated effort occurs for the resolution of such problems. Documentation should indicate that the commanding officer of a facility has taken positive, aggressive

action within the command structure which supports risk management functions, in order to avoid potentially compensable events.

7. Patient Satisfaction

During an interview which was conducted as part of the authors' thesis research, a NAVMEDCOM Judge Advocate General representative stated that one of the most frequently cited reasons for malpractice litigation is patient perception of substandard care caused by physician apathy. Because of the multitude of problems which arise at a MTF, the inclination may be to place such patient complaints at a low priority. However, thorough assessment of complaints may reveal potentially serious, yet previously overlooked problems, which if not resolved may result in the perception of less than satisfactory patient care, and increased risk of malpractice litigation.

This "key variable" relates, once again, to all three of the categories identified during the authors' malpractice litigation case review. While patient satisfaction is not directly measurable, it may be assessed through documentation obtained from sources such as patient contact points, patient satisfaction surveys, incident reports, and direct patient complaints to MTF medical and nursing staff.

Although patient dissatisfaction may be an indication of actual or perceived problems at a MTF, the intent of this "key variable" is to determine whether a mechanism is in

place to determine if complaints are in fact valid, and if so, whether such problems are resolved. This "key variable" requires that there be documented evidence of actions taken to address all patient complaints. Furthermore, the patient satisfaction "key variable" requires evidence of the steps taken to resolve those problems which are determined to be valid.

8. Quality Assurance Program Support

The final "key variable" proposed by the authors relates to the failures category discussed in the authors' malpractice litigation review, and is intended to assess command failure to support a specific component of the organizational system: the quality assurance program.

The first issue addressed by the quality assurance program support "key variable" is that of quality assurance staff qualifications. The information required for this part of the quality assurance program support "key variable" includes an assessment of the qualifications which staff members possess prior to assignment to critical positions within a MTF QA department, and the frequency of staff rotation through the department.

For example, command support is not indicated in a quality assurance program where persons such as the physician head/QA advisor are not required to have received formal training in quality assurance prior to assignment to that position, or are assigned because of lack of performance in

previous positions. Furthermore, lack of command support may be indicated by excessive staff rotation to and from the quality assurance department, as such frequent rotation may lead to a lack of continuity in the quality assurance program.

A recent visit by the authors to a major naval hospital revealed that the facility's physician head/QA advisors had spent, on average, only eight months in the position prior to transfer. Moreover, QA training for most of the physician head/QA advisors had consisted of nothing more than having served on departmental committees.

Another important component of the quality assurance program support "key variable" is the assessment of QA department administrative support. The authors fully realize that administrative support has been reduced throughout NAVMEDCOM because of civilian manpower reductions, and that furthermore, military manpower limitations may exist within a given facility. Sufficient administrative support is nevertheless essential for the proper functioning of the QA department. A positive indication for the quality assurance program support "key variable" would therefore be indicated by adequate administrative support within the QA department.

During the authors' visit to this same naval hospital, one of the recurring complaints discovered was the absolute lack of clerical support within the QA department. The QA coordinator at this facility stated that he had requested clerical support from the Executive Officer of the MTF on

numerous occasions, with negative results. As a result of this clerical support shortage, the QA department physician head/QA advisor, a Navy Captain, was required to devote a significant portion of her time to typing and filing, as opposed to more substantive efforts in the quality assurance program.

The final aspect of the quality assurance program support "key variables" is meant to assess the amount of command backing received on recommendations emanating from within the QA department. Although the quality assurance department may make superb recommendations, if these recommendations are not subsequently implemented, the effectiveness of a quality assurance program may be severely questioned.

If resistance to the implementation of such recommendations occurs, it may become necessary for the Commanding Officer, or others in positions of authority, to become actively involved in the enforcement process. This final aspect of the quality assurance program support "key variable" is meant to assess the degree of such support, in order to provide an indication as to the effectiveness of a quality assurance program.

V. CONCLUSIONS AND RECOMMENDATIONS

It is the authors' opinion that the Naval Medical Command has developed a quality assurance instruction which provides guidance that would enable a MTF to meet the minimum quality assurance accreditation standards imposed by the Joint Commission for Accreditation of Hospitals, providing the facility adheres to the requirements of the instruction. If it was NAVMEDCOM's intent to merely meet minimum JCAH quality assurance standards, they have achieved that goal. However, to fully achieve its stated goal of providing the best quality of patient care within available resources, NAVMEDCOM must affect certain changes in their quality assurance instruction. Furthermore, the authors question the underlying motivation within NAVMEDCOM regarding the actual intent of the quality assurance program.

The authors believe that the QUALITY ASSURANCE GUIDE should more clearly emphasize the Commanding Officer's overall responsibility for the success of his facility's quality assurance program. Although the instruction clearly states that the Commanding Officer bears ultimate responsibility for the quality assurance program, it implies that he can delegate this responsibility to the Executive Officer. It is the authors' opinion that unless the instruction addresses the requirement that the Commanding Officer take an active

role in the quality assurance program, then the success of the program is questionable.

Another shortcoming of the QUALITY ASSURANCE GUIDE is the failure to emphasize the requirement for training and continuity of personnel within a QA department. The instruction should stress the requirement for training individuals in the field of quality assurance prior to assignment to quality assurance department key positions. Furthermore, the instruction should emphasize the necessity for continuity of individual assignments once personnel are placed in key positions within a quality assurance department.

The major deficiency noted in the QUALITY ASSURANCE GUIDE is the lack of a direct approach in addressing medical staff involvement in the quality assurance program. The QUALITY ASSURANCE GUIDE should be more explicit regarding required medical staff involvement in the quality assurance program to parallel other Navy instructions which direct certain individuals to perform specific actions. Consequently, the authors believe that the instruction should directly address the requirement for medical staff involvement with such matters as peer review, acceptance of quality assurance department recommendations, and concurrent medical records review.

The final deficiency noted by the authors in the QUALITY ASSURANCE GUIDE was the lack of specific guidance for the development of support service (ancillary departments) unit

QA plans. The authors feel that since certain MTF's may lack personnel with sufficient experience and training necessary for the initial establishment of a quality assurance program for their particular support services, the instruction should provide more specific examples for such.

A review of recent medical malpractice litigation cases filed against the Navy and interviews with several individuals familiar with the quality assurance program led the authors to develop a set of "key variables" with which to assess the adequacy of an existing MTF quality assurance program. Physician qualifications, peer review, medical staff statistical reviews, medical records, panic devices, risk management, patient satisfaction, and quality assurance program support were areas which the authors deemed essential components for management control of a quality assurance program. As a result of these findings, the authors developed "key variables" which utilize these areas as sources of information which will enable a manager or an auditor to assess a quality assurance program.

While it is apparent that NAVMEDCOM has met minimum JCAH quality assurance standards with the development of the QUALITY ASSURANCE GUIDE, and that a manager might utilize the "key variables" developed by the authors to assess and improve an existing quality assurance program, this alone is not sufficient to guarantee the best quality of patient care within the resources available. There must be a sincere

desire and total commitment on the part of every individual involved in providing patient care, from the Surgeon General of the Navy to the most junior member of a medical facility, to provide the absolute best quality of care possible. Unless this commitment exists, it would be unrealistic to expect noteworthy improvements in the quality of patient care provided within the Navy.

Throughout the course of our research, the authors have been troubled by the seeming lack of emphasis indicated by NAVMEDCOM for achieving their stated goal with regard to quality assurance. A NAVMEDCOM goal to strive to provide the best quality of patient care requires a sincere desire and commitment present at all levels of the chain of command. It is not evident that this is the case. It is our impression that at certain levels within the chain of command, the quality assurance program is viewed as "just one more administrative requirement" that must be fulfilled. Thus one must question whether the intent in the development of the QUALITY ASSURANCE GUIDE was to provide the best quality patient care, or to simply provide a mechanical means by which to reduce risk, and in turn, dollar losses resulting from malpractice litigation.

A nuclear engineer on a Navy submarine is taught to realize the grave implications of failure, and as a result is devoted to perfection in his field of expertise. This should be no less true for those who are responsible for

providing medical care. The nuclear engineer is required to continuously review and evaluate his on-the-job performance; it should be no less incumbent upon those providing patient care to do the same.

APPENDIX A

MALPRACTICE CASE REVIEW CRITERIA
CASE NUMBER/IDENTIFICATION

1. Structure.

   A. Facility type:

      1.) Primary Care
      2.) Secondary Care
      3.) Tertiary Care

2. Location within facility.

3. Persons involved in incident.

   A. Non-medical staff/support personnel

   B. Medical staff

4. Person/persons judged responsible.

5. Brief description of case.

6. QA/Risk Management involvement.

7. Chronology of events.

   A. First time suspected medico-legal problem reported.

   B. How medico-legal problem handled within command.

   C. Results of medico-legal actions taken.

8. Subjective assessment/investigative opinion as to how incident could have been avoided.

9. Any obvious key variables/issues which might have avoided litigation.

10. Contributory Factors.

11. Case outcome.

A. Won . . . why if known

B. Lost . . . why if known

12. Cause of Litigation:

A. Knowledge

1.) Physician staff, Nursing staff, other professionals

2.) Support (Ancillary services) staff, including ambulance drivers, etc.

3.) Facility, including administrative staff, engineers, accountants etc.

B. Negligence

1.) Overt Act: Refusal to come in, refusal to accept responsibility, etc.

2.) Covert Act: General lack of concern, attitude, etc.

C. Failure

1.) Equipment

2.) Facility

3.) Staff

4.) Combination of the above

13. Preventable/Nonpreventable

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